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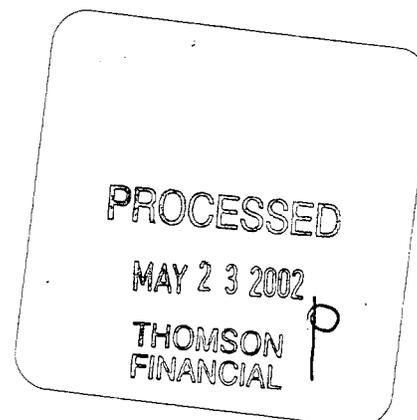
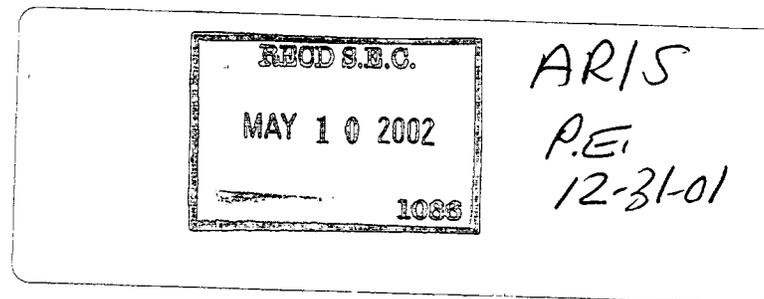
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TOMORROW



TRIPATH IMAGING, INC.

**TRIPATH IMAGING, INC.**

780 Plantation Drive  
Burlington, North Carolina 27215  
(336) 222-9707

**NOTICE OF ANNUAL MEETING OF STOCKHOLDERS**

*To be held on May 23, 2002*

Notice is hereby given that the 2002 Annual Meeting of Stockholders of TriPath Imaging, Inc. will be held on Thursday, May 23, 2002, at 10:00 a.m. at the Country Suites, 3211 Wilson Drive, Burlington, North Carolina, to consider and act upon the following matters:

1. To elect two members of our Board of Directors to serve for three-year terms as Class II Directors.
2. To approve an amendment to our Restated Certificate of Incorporation to increase the number of authorized shares of our common stock by 49,000,000 shares from 49,000,000 to 98,000,000 shares.
3. To approve an amendment to our Amended and Restated 1996 Equity Incentive Plan to increase the number of shares of our common stock available for issuance under the plan by 1,725,000 shares.
4. To transact such other business as may properly come before the meeting or any adjournments thereof.

Only stockholders of record at the close of business on April 12, 2002 will be entitled to vote at the meeting.

**IT IS IMPORTANT THAT YOUR SHARES BE REPRESENTED AT THE MEETING. THEREFORE, WHETHER OR NOT YOU PLAN TO ATTEND THE MEETING, PLEASE COMPLETE YOUR PROXY AND RETURN IT IN THE ENCLOSED ENVELOPE, WHICH REQUIRES NO POSTAGE IF MAILED IN THE UNITED STATES. IF YOU ATTEND THE MEETING AND WISH TO VOTE IN PERSON, YOUR PROXY WILL NOT BE USED.**

By order of the Board of Directors,  
Steven N. Farber  
*Secretary*

April 30, 2002

**TABLE OF CONTENTS**

	<u>Page</u>
GENERAL INFORMATION .....	1
SHARE OWNERSHIP .....	3
PROPOSAL 1     ELECTION OF DIRECTORS .....	6
PROPOSAL 2     APPROVAL OF AMENDMENT TO OUR RESTATED CERTIFICATE OF INCORPORATION .....	10
PROPOSAL 3     APPROVAL OF AMENDMENT TO OUR EQUITY INCENTIVE PLAN .....	12
EXECUTIVE COMPENSATION .....	16
Compensation Committee Report on Executive Compensation .....	16
Elements of Executive Compensation .....	16
SUMMARY COMPENSATION TABLE .....	18
OPTION GRANTS IN LAST FISCAL YEAR .....	19
Comparative Stock Performance Graph .....	21
COMPENSATION COMMITTEE INTERLOCKS, INSIDER PARTICIPATION AND CERTAIN TRANSACTIONS .....	22
REPORT OF THE AUDIT COMMITTEE .....	22
SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE .....	23
INFORMATION CONCERNING AUDITORS .....	23
STOCKHOLDER PROPOSALS FOR THE 2003 ANNUAL MEETING .....	23
ADVANCE NOTICE PROVISIONS FOR STOCKHOLDER PROPOSALS AND NOMINATIONS .....	23
OTHER MATTERS .....	24
APPENDIX A — TRIPATH IMAGING, INC. AUDIT COMMITTEE CHARTER .....	A-1
APPENDIX B — TRIPATH IMAGING, INC. — AMENDED AND RESTATED 1996 EQUITY INCENTIVE PLAN .....	B-1

TRIPATH IMAGING, INC.  
780 Plantation Drive  
Burlington, North Carolina 27215  
(336) 222-9707

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**PROXY STATEMENT**

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**GENERAL INFORMATION**

Our Board of Directors is soliciting your proxy for use at our 2002 Annual Meeting of Stockholders to be held on Thursday, May 23, 2002, at 10:00 a.m. at the Country Suites, 3211 Wilson Drive, Burlington, North Carolina, and at any adjournments of the meeting. This Proxy Statement and the enclosed proxy card are first being mailed or given on or about April 30, 2002 to all of our stockholders entitled to notice of and to vote at the meeting.

**Who can vote.** You may vote your shares of our common stock at the meeting if you were a stockholder of record at the close of business on April 12, 2002, the record date. On that date, we had 37,454,684 shares of common stock issued and outstanding. You are entitled to one vote for each share of common stock that you held on the record date.

**How to vote your shares.** You may vote your shares either by proxy or by attending the annual meeting and voting in person. If you choose to vote by proxy, please complete, date, sign and return the proxy card in the enclosed postage-prepaid envelope. The proxies named in the proxy card will vote your shares in accordance with your voting instructions given on the proxy card. If you sign the proxy card but do not give specific instructions with respect to one or more of the proposals contained in this proxy statement, the proxies will vote your shares in favor of each of the proposals as recommended by our Board of Directors. Even if you plan to attend the meeting, please complete and mail your proxy card to ensure that your shares are represented at the meeting. If you attend the meeting, you can still revoke your proxy by voting in person.

**Proposals to be considered at the annual meeting.** The principal business expected to be transacted at the meeting, as more fully described below, will be the election of two directors, an amendment to our Restated Certificate of Incorporation to increase the number of shares of common stock we are authorized to issue and an amendment to our Amended and Restated 1996 Equity Incentive Plan (the "Equity Incentive Plan") to increase the number of shares of common stock we may issue under the plan.

**Quorum.** A quorum of stockholders is required in order to transact business at the meeting. A majority in interest of the issued and outstanding shares of common stock, represented at the meeting in person or by proxy, constitutes a quorum for the transaction of business.

**Number of votes required.** The number of votes required to approve each of the three proposals that are scheduled to be presented at the meeting is as follows:

<u>Proposal</u>	<u>Required Vote</u>
• Election of two nominees as directors.	Affirmative vote representing a plurality of the votes cast for or against the nominee.
• Amendment to our charter to increase the authorized number of shares of common stock.	Affirmative vote representing a majority of the outstanding shares of our common stock.
• Amendment to our Equity Incentive Plan to increase the number of shares available for issuance under the plan.	Affirmative vote representing a majority of the shares of our common stock present or represented at the meeting and entitled to vote.

**Abstentions and broker non-votes.** A broker non-vote on a proposal results from a proxy submitted by a broker that does not indicate a vote for one or more proposals because the broker does not have discretionary voting authority and the customer did not send the broker instructions on how to vote on the proposal. If the broker does not have instructions with respect to a matter, and is barred by law or by Nasdaq regulations from exercising its discretionary voting authority in the particular matter, then the shares will not be voted on the matter. Abstentions and broker non-votes will be counted for purposes of determining the presence of a quorum but will not be counted as votes cast in the election of directors. In voting on the proposal to amend our charter, abstentions and broker non-votes will count as votes against the proposal. In voting on the proposal to amend the Equity Incentive Plan, abstentions will count as votes against the amendment and broker non-votes will not be counted.

**Discretionary voting by proxies on other matters.** The meeting is called for the purposes set forth in the notice. Aside from the three proposals discussed in this proxy statement, we do not know of any other proposals that may be presented at the annual meeting. If another matter is properly presented for consideration at the meeting, the persons named in the accompanying proxy card will exercise their discretion in voting on the matter. It is the intention of the persons named in the proxy to vote in accordance with their best judgment on any such matter.

**How you may revoke your proxy.** You may revoke the authority granted by your executed proxy at any time before we exercise it by submitting a written notice of revocation or a duly executed proxy bearing a later date to our Assistant Secretary or by voting in person at the meeting. If your shares are held in a brokerage or bank account, you must make arrangements with your broker or bank to vote your shares in person or to revoke your proxy.

**Expenses of solicitation.** We will bear all costs of soliciting proxies. We have retained Georgeson Shareholder to assist with the solicitation of proxies for a fee of approximately \$6,000. We will, upon request, reimburse brokers, custodians and fiduciaries for out-of-pocket expenses incurred in forwarding proxy solicitation materials to the beneficial owners of our common stock held in their names. In addition to solicitations by mail, our directors, officers and employees may solicit proxies from stockholders in person or by other means of communication, including telephone, facsimile and e-mail, without additional remuneration.

## SHARE OWNERSHIP

The following table and footnotes set forth certain information regarding the beneficial ownership of our common stock as of April 1, 2002 by:

- each person known by us to own beneficially 5% or more of our common stock;
- each Named Executive Officer (as defined in "Executive Compensation" below);
- each of our directors; and
- all of our current directors and executive officers as a group.

The number of shares beneficially owned by each person listed below includes any shares over which the person has sole or shared voting or investment power as well as shares which the person has the right to acquire upon the exercise of any options or other rights exercisable within the 60-day period following April 1, 2002. Unless otherwise noted, each person has sole investment and voting power over the shares listed in the table. The percentage ownership of each person listed in the table was calculated using the total number of shares outstanding on April 1, 2002, plus any shares that person could acquire upon the exercise of any options or other rights exercisable within the 60-day period following April 1, 2002.

<u>Beneficial Owner</u>	<u>Shares of Common Stock Beneficially Owned</u>	
	<u>Shares</u>	<u>Percent</u>
Roche Holding Ltd. affiliated entities(1) ..... Grenzacherstrasse 124 Postfach CH-4070 Basel Switzerland	12,950,680	34.58%
Becton, Dickinson and Company ..... 1 Becton Drive Franklin Lakes, NJ 07417	2,500,000	6.67%
Credit Suisse First Boston(2) ..... 11 Madison Avenue New York, New York 10010	2,170,098	5.79%
Zesiger Capital Group LLC(3) ..... 320 Park Avenue, 30th Floor New York, NY 10022	2,062,803	5.51%
Paul R. Sohmer, M.D.(4) .....	391,957	1.05%
Stephen P. Hall(5) .....	18,748	*
Ray W. Swanson, Jr.(6) .....	37,082	*
John G.R. Hurrell(7) .....	10,415	*
Thomas Gahm, Ph.D.(8) .....	201,051	*
Mary K. Norton(9) .....	101,365	*

<u>Beneficial Owner</u>	<u>Shares of Common Stock Beneficially Owned</u>	
	<u>Shares</u>	<u>Percent</u>
Robert E. Curry, Ph.D.(10) .....	2,176,098	5.81%
Haywood D. Cochrane, Jr.(11) .....	40,000	*
Thomas A. Bonfiglio, M.D.(12) .....	32,064	*
David A. Thompson(13) .....	60,699	*
Richard A. Charpie, Ph.D.(14) .....	6,000	*
David H. Robison(15) .....	146,612	*
Roger W. Martin(16) .....	49,788	*
All current executive officers and directors as a group (9 persons) (17) .....	2,784,524	7.43%

\* Indicates less than 1%.

- (1) Includes 5,000,000 shares held by Roche International Ltd., a Bermuda corporation ("Roche") and 2,950,680 shares held by Roche Image Analysis Systems, Inc., a Delaware corporation ("RIAS"). Roche is a wholly-owned subsidiary of Canadian Pharmholding Ltd., a Canadian corporation ("Pharmholding"), which is in turn a wholly-owned subsidiary of SAPAC Corporation Ltd., a corporation organized under the laws of the Province of New Brunswick, Canada ("SAPAC"). RIAS is a wholly-owned subsidiary of Roche Holdings, Inc., a Delaware corporation ("Holdings Inc."), which is in turn a wholly-owned subsidiary of Roche Finance Ltd., a Swiss company ("Finance"). SAPAC and Finance are each wholly-owned subsidiaries of Roche Holding Ltd., a Swiss company ("Holding Ltd."). Pursuant to an agreement, Professor Kurt Jenny has the power to vote a majority of the voting securities of Holding Ltd. Each of Professor Jenny, Holding Ltd., Finance, Holdings Inc., SAPAC and Pharmholding expressly disclaim beneficial ownership of the shares. Also includes 5,000,000 shares that may be acquired by Roche within 60 days of April 1, 2002 upon the exercise of warrants. The above information is based on a Schedule 13D filed by Roche with the U.S. Securities and Exchange Commission ("SEC") on November 15, 2000.
- (2) Consists of 1,887,760 shares held by Sprout Capital VII, L.P. ("Sprout"); 217,009 shares held by DLJ First ESC, L.L.C. ("DLJ First"); 43,401 shares held by DLJ Capital Corporation ("DLJ Capital"); and 21,928 shares held by the Sprout CEO Fund, L.P. ("Sprout CEO"). DLJ Capital is the managing general partner of Sprout and Sprout CEO and has voting and investment control over the shares held by those two entities. DLJ LBO Plans Management Corporation ("DLJ LBO") is the manager of DLJ First and has voting and investment control over the shares held by DLJ First. DLJ Capital and DLJ LBO both are wholly-owned subsidiaries of Credit Suisse First Boston (USA), Inc.
- (3) Zesiger Capital Group LLC disclaims beneficial ownership of these securities which are held in discretionary accounts it manages. The above information is based on a Schedule 13G filed by Zesiger Capital Group LLC with the SEC on February 14, 2002.
- (4) Consists entirely of shares that may be acquired within 60 days of April 1, 2002 upon the exercise of options.

- (5) Consists entirely of shares that may be acquired within 60 days of April 1, 2002 upon the exercise of options.
- (6) Includes 27,082 shares that may be acquired within 60 days of April 1, 2002 upon the exercise of options.
- (7) Consists entirely of shares that may be acquired within 60 days of April 1, 2002 upon the exercise of options.
- (8) Includes 117,381 shares that may be acquired within 60 days of April 1, 2002 upon the exercise of options.
- (9) Consists entirely of shares that may be acquired within 60 days of April 1, 2002 upon the exercise of options.
- (10) Consists of 2,170,098 of the shares held by Sprout, DLJ First, DLJ Capital and Sprout CEO as described in note (2). Dr. Curry is a consultant to DLJ Capital Corporation and acts as attorney-in-fact with respect to its investment in us and thus may be considered the beneficial owner of the shares described in note (2). Dr. Curry disclaims beneficial ownership of such shares except to the extent of his pecuniary interest. Also includes 6,000 shares that may be acquired within 60 days of April 1, 2002 upon the exercise of options.
- (11) Includes 20,000 shares that may be acquired within 60 days of April 1, 2002 upon the exercise of options.
- (12) Includes 31,064 shares that may be acquired within 60 days of April 1, 2002 upon the exercise of options.
- (13) Includes 56,748 shares that may be acquired within 60 days of April 1, 2002 upon the exercise of options.
- (14) Consists entirely of shares that may be acquired within 60 days of April 1, 2002 upon the exercise of options.
- (15) Consists entirely of shares that may be acquired within 60 days of April 1, 2002 upon the exercise of options.
- (16) Consists entirely of shares that may be acquired within 60 days of April 1, 2002 upon the exercise of options.
- (17) See notes (4) through (7) and (10) through (14) above. Includes 564,596 shares that may be acquired within 60 days of April 1, 2002 upon the exercise of options.

**PROPOSAL 1**  
**ELECTION OF DIRECTORS**

**General**

In accordance with our by-laws, our Board of Directors has fixed the number of directors at seven for the coming year. Our Board of Directors is divided into three classes, with the members of each class elected for three-year terms and the term for each class expiring in successive years.

At the meeting, two Class II directors will be elected to hold office for three years until their respective successors are duly elected and qualified. Our Board of Directors has nominated Haywood D. Cochrane, Jr. and Robert L. Sullivan for election for terms expiring in 2005. Mr. Cochrane is currently one of our directors and has consented to be nominated and to serve if elected. Mr. Sullivan will be a new director and has also consented to be nominated and to serve if elected. In the event that either Mr. Cochrane or Mr. Sullivan is unable to serve as a director, the shares represented by proxy will be voted for the person, if any, designated by our Board of Directors to replace Mr. Cochrane or Mr. Sullivan. In the event that a vacancy occurs during either of their three year terms, such vacancy may be filled by our Board of Directors for the remainder of the full term.

Following the annual meeting, there will be a vacancy among the Class I directors, whose term expires in 2004. Under our by-laws, our Board of Directors may fill this vacancy with a director who would serve until the 2004 Annual Meeting of Stockholders.

Under our by-laws, directors must be elected by a plurality of votes cast. Abstentions, votes withheld and broker non-votes will not be treated as votes cast and, therefore, will not affect the outcome of the election.

The following table contains certain information about the nominee for election to the Board of Directors and about each other person whose term of office as a director will continue after the meeting.

<u>Name and Age</u>	<u>Business Experience During Past Five Years and Other Directorships</u>	<u>Director Since</u>	<u>Present Term Expires</u>
<b>Nominee for Director:</b>			
<b>Class II Director</b>			
Haywood D. Cochrane, Jr. Age: 53	Mr. Cochrane has served as the Chief Executive Officer of Meridian Corporate Healthcare ("Meridian"), a national provider of employer-sponsored healthcare services to large and mid-sized employers, in Nashville, Tennessee since February 1997. Prior to joining Meridian, Mr. Cochrane served as a consultant to Laboratory Corporation of America Holdings ("LabCorp"), a national clinical laboratory testing company. From April 1995 to November 1996, he was Executive Vice President, Chief Financial Officer and Treasurer of LabCorp. Mr. Cochrane was an employee of National Health Laboratories, Inc. ("NHL") from June 1994 to April 1995, following NHL's acquisition of his former employer Allied Clinical Laboratories, Inc. ("Allied"). Mr. Cochrane was President and Chief Executive Officer of Allied from its formation in 1989 until its acquisition by NHL in June 1994. Mr. Cochrane is currently a director at JDN Realty, Inc., Ameripath, Inc. and Sonus Corp., all publicly traded companies as well as CHD Meridian. Mr. Cochrane received a B.A. in political science from the University of North Carolina at Chapel Hill.	1999	2002

<u>Name and Age</u>	<u>Business Experience During Past Five Years and Other Directorships</u>	<u>Director Since</u>	<u>Present Term Expires</u>
Robert L. Sullivan Age: 64	Mr. Sullivan is retired from Chiron Diagnostics Corporation, a manufacturer and marketer of medical diagnostic equipment and supplies, where from 1985 to March 1999 he served as Senior Vice President — Finance. From 1962 to 1985, Mr. Sullivan held several operating and financial positions with Corning Glass Works. Mr. Sullivan is also a director of Colorado MEDtech, Inc., a medical products company.	—	—
<b>Continuing Directors: Class III Directors</b>			
Thomas A. Bonfiglio, M.D. Age: 59	Dr. Bonfiglio serves as Senior Attending Pathologist and Head, Division of Pathology at The Rochester General Hospital in Rochester, New York. Dr. Bonfiglio is also a Clinical Professor at the University of Rochester's Department of Pathology and Laboratory Medicine, where he has maintained various academic positions since 1971. Since 1969, Dr. Bonfiglio has held pathology positions at various hospitals, most recently as Pathologist in Chief at Strong Memorial Hospital from 1989 to 1997. He is a past president of the American Society of Clinical Pathologists and the American Society of Cytopathology and has authored numerous medical publications. He was previously a director of NeoPath, Inc., until the acquisition of NeoPath by us on September 30, 1999.	1999	2003
David A. Thompson Age: 60	Mr. Thompson retired in June 1995 from Abbott Laboratories ("Abbott"), a manufacturer and distributor of pharmaceutical and nutritional products, where he served in various capacities since 1964. From August 1983 to July 1990, he was Abbott's Vice President, Diagnostic Operations and President, Diagnostics Division. From July 1990 to June 1994, he was Abbott's Senior Vice President, Diagnostic Operations and President, Diagnostics Division, and from June 1994 until his retirement, he was Abbott's Senior Vice President, Strategic Improvement Processes. Mr. Thompson is currently Chief Executive Officer of Diagnostic Marketing Strategies, a private consulting firm. Mr. Thompson is also a director of Third Wave Technologies, Inc. and St. Jude Medical, Inc. He was previously a director of NeoPath, Inc., from June 1995 until the acquisition of NeoPath by us on September 30, 1999.	1999	2003

<u>Name and Age</u>	<u>Business Experience During Past Five Years and Other Directorships</u>	<u>Director Since</u>	<u>Present Term Expires</u>
<b>Class I Directors</b>			
Robert E. Curry, Ph.D. Age: 55	Since July 1, 2001, Dr. Curry has been engaged as a consultant to DLJ Capital Corporation, a wholly-owned subsidiary of Credit Suisse First Boston (USA), Inc. ("CSFB"). He joined the Sprout Group ("Sprout"), a submanager of various venture capital funds within the CSFB organization, as a general partner in May 1991. Prior to joining Sprout, Dr. Curry served in various capacities with Merrill Lynch R&D Management and Merrill Lynch Venture Capital from 1984, including as President of both organizations from January 1990 to May 1991. Previously, Dr. Curry was a Vice President of Becton, Dickinson and Company, a pharmaceutical company, from May 1980 to July 1984, and General Manager of Bio-Rad Laboratories Inc.'s Diagnostics Systems Division from August 1976 to May 1980. He currently is a director of Adeza Biomedical, Inc., Instrumentation Metrics, Inc., Emerald BioAgriculture, Inc., Prometheus Laboratories, Inc., Photon Technology International, Inc. and Pathology Partners, Inc. Dr. Curry received a B.S. from the University of Illinois, and a M.S. and Ph.D. in chemistry from Purdue University.	1996	2004
Paul R. Sohmer, M.D. Age: 53	Dr. Sohmer has served as our Chairman of the Board since November 2000, and as our President and Chief Executive Officer since June 2000. Prior to joining us, Dr. Sohmer served as the President and Chief Executive Officer of Neuromedical Systems, Inc., a supplier of cytology screening and anatomic pathology diagnostic equipment and services to laboratories, from 1997 through 1999. From 1996 until 1997, Dr. Sohmer served as President of a consulting firm which he founded. From 1993 to 1996, he served as President and Chief Executive Officer of Genetrix, Inc., a genetic services company based in Scottsdale, Arizona. From 1991 through 1993, Dr. Sohmer was the Corporate Vice-President of Professional Services and President of the Professional Services Organization for Nichols Institute, a clinical laboratory company, where he was responsible for sales, marketing, information systems, logistics, and clinical studies. From 1985 until 1991, Dr. Sohmer served as the President and Chief Executive Officer of Pathology Institute in Berkeley, California, during which time he founded and served as Medical Director of the Chiron Reference Laboratory. Dr. Sohmer received a B.A. degree from Northwestern University and an M.D. from Chicago Medical School.	2000	2004

**OUR BOARD OF DIRECTORS RECOMMENDS A VOTE FOR THE ELECTION OF HAYWOOD D. COCHRANE, JR. AND ROBERT L. SULLIVAN AS CLASS II DIRECTORS.**

#### **Committees of the Board**

Our Board of Directors has standing Audit and Compensation Committees. Additionally, our Board of Directors formed a Nominating Committee in February 2002 for the purpose of nominating a suitable candidate to fill the vacancy on our Board of Directors created by Dr. Charpie's resignation following the 2002 annual meeting.

### *The Audit Committee*

Our Audit Committee currently consists of Dr. Richard A. Charpie, David A. Thompson and Haywood D. Cochrane, Jr. each of whom is independent as defined by applicable Nasdaq National Market standards governing the qualifications of audit committee members. Following the 2002 annual meeting, Dr. Charpie will no longer serve on the Audit Committee due to the expiration of his term as a director. Mr. Sullivan, if elected as a director, will be appointed to fill the vacancy on the Audit Committee upon Dr. Charpie's resignation. The Audit Committee assists our Board of Directors in the discharge of its duties and responsibilities by selecting and evaluating our independent auditors, providing our Board of Directors with an independent review of our financial health and the reliability of our financial contracts and financial reporting systems. Our Audit Committee reviews the general scope of our annual audit, the fee charged by our independent auditors and other matters relating to internal control systems. Our Audit Committee held three meetings in 2001. Our Audit Committee operates under a written charter adopted by our Board of Directors on April 27, 2000. On April 22, 2002, our Audit Committee adopted an amended charter, a copy of which is included as Appendix A to this proxy statement. See "Report of the Audit Committee" in this proxy statement.

### *Compensation Committee*

Our Compensation Committee currently consists of Drs. Curry and Bonfiglio. The Compensation Committee determines the compensation paid to all of our executive officers, including our Chief Executive Officer. Our Compensation Committee's responsibilities include, reviewing the performance of our Chief Executive Officer and our other executive officers and making determinations as to their cash and equity-based compensation and benefits, and administering employee stock option grants and stock awards made under our Equity Incentive Plan. Our Compensation Committee held three meetings in 2001.

### *Nominating Committee*

In February 2002, our Board of Directors established a Nominating Committee to identify and screen potential candidates to be nominated to fill the vacancy on our Board of Directors created by the expiration of Dr. Charpie's term as a director following the 2002 annual meeting. Dr. Paul R. Sohmer, Dr. Bonfiglio, and Mr. Thompson were appointed to our Nominating Committee with Dr. Sohmer appointed as Chair of the committee. Our Nominating Committee has held one meeting at which it nominated Mr. Sullivan to stand for election as a director. Our Nominating Committee will not consider nominees recommended by stockholders.

### **Attendance at Meetings**

During the year ended December 31, 2001, our Board of Directors held nine meetings. Each of our directors attended at least 75% of our Board of Directors meetings and meetings of committees of our Board of Directors of which they were a member, except that Mr. Thompson attended 67% of the aggregate of such meetings.

## **Director Compensation**

All of our non-employee directors who beneficially own (as determined pursuant to Rule 13d-3 under the Securities Exchange Act of 1934, as amended) less than 3% of our outstanding common stock are paid \$10,000 per year for service as a director, payable quarterly.

In addition, our directors receive compensation for their service on our Board of Directors pursuant to our 1997 Director Stock Option Plan (the "Director Plan"), which our Board of Directors and stockholders adopted in June 1997 and amended in June 2000. All of our directors who (1) are not our employees, (2) do not beneficially own 3% or more of our outstanding stock and (3) are not otherwise excluded by resolution of our Board of Directors (the "Eligible Directors"), are currently eligible to participate in our Director Plan. There are 300,000 shares of common stock reserved for issuance under our Director Plan. Upon the election or reelection of an Eligible Director, such director will be automatically granted an option to purchase 30,000 shares of our common stock. Options become exercisable with respect to 10,000 shares on each anniversary of the date of grant for a period of three years, provided that the director is still serving on our Board of Directors at the opening of business on such date. Each option has a term of ten years. The exercise price for each option is equal to the last sales price for our common stock on the business day immediately preceding the date of grant, as reported on the Nasdaq National Market. The exercise price may be paid in cash, shares of common stock or a combination of both.

## **PROPOSAL 2**

### **APPROVAL OF AN AMENDMENT TO OUR RESTATED CERTIFICATE OF INCORPORATION**

#### ***General***

Our Restated Certificate of Incorporation currently authorizes the issuance of 49,000,000 shares of common stock and 1,000,000 shares of preferred stock. On April 22, 2002, our Board of Directors approved an amendment to our Restated Certificate of Incorporation to increase the number of authorized shares of our common stock from 49,000,000 shares to 98,000,000 shares, subject to stockholder approval.

#### ***Current Use of Shares***

As of April 1, 2002, there were 37,454,684 shares of common stock outstanding or reserved for issuance (including shares subject to outstanding options), with no shares held by us in treasury. This total number of shares includes 4,996,325 shares reserved for issuance or issued under our Equity Incentive Plan, 1,000,000 shares reserved for issuance or issued under our 2001 Employee Stock Purchase Plan and 300,000 shares reserved for issuance or issued under our Director Plan. In addition, as described in Proposal 3 below, we are asking the stockholders to approve an increase of 1,725,000 shares for issuance under the Equity Incentive Plan. As of the date of this proxy statement, there were no shares of preferred stock issued or outstanding.

*Purpose of the Proposed Amendment*

Our Board of Directors believes that increasing the number of authorized shares of our common stock is essential to ensure that we continue to have an adequate number of shares of common stock available for future use. Our Board of Directors believes that the proposed increase will make available a sufficient number of authorized shares of common stock for future issuances including, financings, corporate mergers and acquisitions, use in employee benefit plans, stock splits, stock dividends or other corporate purposes. The availability of additional shares of common stock will provide us with greater flexibility in taking any of these actions and would allow us to issue shares of our common stock without the delay or expense of obtaining stockholder approval, except to the extent required by state law or Nasdaq requirements for particular transactions. As of the date of this proxy statement, we had no agreements, commitments or plans with respect to the sale or issuance of additional shares of common stock, other than with respect to those shares of common stock reserved for issuance as noted above.

*Effects of the Proposed Amendment*

The proposed amendment would increase the number of shares of our common stock available for issuance, but would have no effect upon the terms of our common stock or the rights of holders of our common stock. Common stockholders are not now, and will not be, entitled to preemptive or other rights to subscribe for additional shares of our common stock. If this proposal is adopted, additional shares of authorized common stock (as well as all currently authorized but unissued shares of common stock) would be available for issuance without further action by the stockholders, subject to Nasdaq stockholder approval requirements for certain issuances of additional shares of common stock. While our Board of Directors will authorize the issuance of additional shares of common stock based on its judgment as to our best interests and that of our stockholders, future issuances of common stock could have a dilutive effect on existing stockholders and on earnings per share. In addition, the issuance of additional shares of common stock, as well as the availability of preferred stock that the Board may issue on such terms as it selects, could have the effect of making it more difficult for a third party to acquire a majority of our outstanding voting stock.

**OUR BOARD OF DIRECTORS BELIEVES THAT THE PROPOSED AMENDMENT IS IN THE BEST INTERESTS OF US AND OUR STOCKHOLDERS AND RECOMMENDS A VOTE FOR THIS PROPOSAL.**

## PROPOSAL 3

### APPROVAL OF AMENDMENT TO OUR EQUITY INCENTIVE PLAN

#### *General*

On June 26, 1997, our stockholders adopted and approved the Equity Incentive Plan and we reserved 2,086,325 shares of common stock for issuance under the plan. On May 26, 1999 and June 1, 2000, our stockholders approved additional amendments to the Equity Incentive Plan to increase the number of shares of common stock available for issuance by 900,000 and 1,585,000 shares, respectively. On January 15, 2002, our Board of Directors approved an amendment to the Equity Incentive Plan to increase the number of shares of common stock available for issuance by 425,000 shares from 4,571,325 shares to 4,996,325 shares. We obtained confirmation from the Nasdaq National Market that the increase of 425,000 shares was immaterial, and, as such, stockholder approval was not required in order to amend the Equity Incentive Plan. Currently, the total number of shares that we may issue under the Equity Incentive Plan is 4,996,325 shares, subject to adjustment for stock splits and similar capital changes. As of April 1, 2002, 232,155 shares remained available for future issuances under the Equity Incentive Plan.

#### *Proposed Amendment to the Equity Incentive Plan*

On February 4, 2002, our Board of Directors approved an amendment to the Equity Incentive Plan, subject to stockholder approval, to increase the number of shares issuable under the Equity Incentive Plan by an additional 1,300,000 shares from 4,996,325 shares to 6,296,325 shares. Our Board of Directors is requesting stockholder approval of the proposed 1,300,000 shares increase, as well as the 425,000 share increase approved by our Board of Directors in January 2002, in order to ensure that all shares of common stock issued pursuant to awards under the Equity Incentive Plan may be treated as incentive stock options under the Internal Revenue Code of 1986, as amended. If the stockholders approve the proposed amendment, the number of shares available for issuance under the Equity Incentive Plan would be increased by a total of 1,725,000 shares. A copy of the Equity Incentive Plan as proposed to be amended is included as Appendix B to this proxy statement.

We need additional shares of common stock for use under the Equity Incentive Plan to ensure that a sufficient number of shares of common stock are available for Awards to eligible persons in the future. If this proposed amendment is not approved by the stockholders, no grants of Awards will be made under the Equity Incentive Plan once Awards covering the shares of our common stock currently available under the Equity Incentive Plan are granted. The proceeds we receive from the exercise of options under the Equity Incentive Plan are used for general corporate purposes.

#### *Summary of the Equity Incentive Plan*

The purpose of the Equity Incentive Plan is to attract and retain employees and consultants and to provide an incentive for these persons to achieve long-range performance goals. The Equity Incentive Plan permits us to grant equity awards, referred to as Awards, to our employees and consultants, including incentive and non-statutory stock options, stock appreciation rights, performance shares, restricted stock and stock units. To date, we have granted only incentive stock options, non-statutory stock options and restricted stock under the Equity Incentive Plan. Any options we grant under the Equity Incentive Plan upon assuming or substituting outstanding grants of an acquired company will not reduce the number of

shares available under the plan. If the proposed amendment is approved by the stockholders, a total of 6,296,325 shares of common stock will be reserved for issuance under the Equity Incentive Plan.

As of April 1, 2002, Awards representing an aggregate of 5,528,004 shares of common stock had been granted, while Awards representing 763,834 shares of common stock had been cancelled, leaving 4,764,170 shares represented by Awards outstanding or exercised. The closing price of our common stock as reported by the Nasdaq National Market on April 1, 2002 was \$5.66.

#### ***Administration and Eligibility***

The Equity Incentive Plan is administered by the Compensation Committee of our Board of Directors. Subject to certain limitations, our Compensation Committee may delegate to one or more of our executive officers the power to make awards to participants who are not our executive officers subject to the reporting requirements of Section 16(a) of the Securities Exchange Act of 1934, as amended, or who are "covered employees" for purposes of Section 162(m) of the Internal Revenue Code. As of April 1, 2002, there were approximately 220 employees eligible to participate in the Equity Incentive Plan.

Awards under the Equity Incentive Plan are granted at the discretion of our Compensation Committee, which determines the recipients and establishes the terms and conditions of each Award, including the exercise price, the form of payment of the exercise price, the number of shares subject to the Award and the time at which such options become exercisable. Although our Compensation Committee has discretion in granting Awards, the exercise price of any incentive stock option, or ISO, may not be less than 100% of the fair market value of our common stock on the date of the grant. Nonstatutory options also are generally granted at fair market value. The maximum number of shares subject to Awards that may be granted to any participant within any fiscal year may not exceed 1,000,000 shares. The term of any ISO granted under the Equity Incentive Plan may not exceed ten years, and no ISO may be granted under the Equity Incentive Plan more than ten years from the Equity Incentive Plan's adoption. When a participant's employment is terminated, vested options are generally cancelled if not exercised within a specified time. An option holder may not transfer an ISO granted under the Equity Incentive Plan other than by will or the laws of descent and distribution. Other Awards are transferable to the extent provided by our Compensation Committee.

#### ***Equity Awards Granted Under the Equity Incentive Plan***

The following table presents information with respect to options granted under the Equity Incentive Plan since its adoption through December 31, 2001, to:

- the officers named in the Summary Compensation Table;
- all executive officers as a group;
- all non-employee directors as a group; and
- all non-executive officer employees as a group.

Other than the grants to non-employee directors described in "ELECTION OF DIRECTORS.— Director Compensation," amounts of future awards under the Equity Incentive Plan are not determinable because, under the terms of the Equity Incentive Plan, these grants are made at the discretion of our Compensation Committee.

<u>Name</u>	<u>Stock Option Awards</u>
Paul R. Sohmer, M.D. .... President and Chief Executive Officer	893,000
Stephen P. Hall ..... Senior Vice President, Chief Financial Officer	100,000
John G.R. Hurrell, Ph.D. .... Senior Vice President, TriPath Oncology, Inc.	100,000
Ray W. Swanson, Jr. .... Senior Vice President of Commercial Operations	100,000
Thomas Gahm, Ph.D. .... Vice President of Computer Science	235,692
Mary K. Norton ..... Vice President of Regulatory/Government Affairs and Quality Assurance	183,122
David H. Robison(1) ..... Vice President of Operations	251,641
Roger W. Martin ..... Vice President of Sales and Marketing(2)	147,500
Executive Officer Group (4 persons) .....	1,193,000
Non-Employee Director Group (5 persons)(3) .....	—
Non-Executive Officer Employee Group (304 persons) .....	4,318,151

- (1) Mr. Robison served as Vice President of Operations until December 31, 2001.
- (2) Mr. Martin served as Vice President of Sales and Marketing until July 2001.
- (3) Our non-employee directors are not eligible to receive options under the Equity Incentive Plan. Any options granted to eligible non-employee directors are granted under our 1997 Director Stock Option Plan.

Of the nominees for election as director, neither Mr. Cochrane nor Mr. Sullivan has received any options under our Equity Incentive Plan. Mr. Cochrane has received options to purchase a total of 30,000 shares under our 1997 Director Stock Option Plan for his service as a director. If elected at the 2002 annual meeting, Mr. Sullivan will also receive options to purchase a total of 30,000 shares under our 1997 Director Stock Option Plan.

## ***Federal Income Tax Consequences Relating to Stock Options***

### ***Incentive Stock Options***

An optionee does not realize taxable income upon the grant or exercise an ISO under the Equity Incentive Plan. If the optionee holds the shares issued upon exercise of an ISO for at least:

- two years from the date of grant; and
- one year from the date of exercise;

then upon sale of the shares, any amount realized in excess of the exercise price is taxed to the optionee as long-term capital gain and any loss sustained will be long-term capital loss. In that event, we may not take a deduction for federal income tax purposes. The exercise of an ISO gives rise to an adjustment in computing alternative minimum taxable income that may result in alternative minimum tax liability for the optionee.

If the optionee disposes of shares of common stock acquired upon the exercise of an ISO before the end of either of the prescribed holding periods, known as a "disqualifying disposition", then the optionee realizes ordinary income in the year of disposition to the extent that the fair market value of the shares on the date of exercise exceeds the exercise price, and we would be entitled to deduct that amount. Any further gain realized by the optionee would be taxed as a short-term or long-term capital gain and would not result in any deduction for us. A disqualifying disposition in the year of exercise will generally avoid the alternative minimum tax consequences of the exercise of an ISO.

### ***Nonstatutory Stock Options***

An optionee does not realize income at the time a nonstatutory option is granted. Upon exercise of the option, the optionee realizes ordinary income in an amount equal to the difference between the exercise price and the fair market value of the shares on the date of exercise. We would receive a tax deduction for the same amount. Upon disposition of the shares, any appreciation or depreciation after the date of exercise is treated as a short-term or long-term capital gain or loss and will not result in any deduction for us.

An optionee who receives any accelerated vesting or exercise of options or stock appreciation rights or accelerated lapse of restrictions on restricted stock in connection with a change in control might be deemed to have received an "excess parachute payment" under federal tax law. In this case, the optionee may be subject to an excise tax, and we may be denied a tax deduction.

**OUR BOARD OF DIRECTORS RECOMMENDS A VOTE FOR THIS PROPOSAL.**

## EXECUTIVE COMPENSATION

The Compensation Committee Report on Executive Compensation and the tables set forth below provide information about the compensation of our executive officers.

### Compensation Committee Report on Executive Compensation

Our executive compensation policy is designed to increase stockholder value by attracting, retaining and motivating executive officers to maximize our performance. Generally, we have set the salaries of our executive officers at slightly below industry averages and provided for significant variable compensation through stock options. Stock option grants are key components of the executive compensation program and are intended to provide executives with an equity interest in the Company to link a meaningful portion of the executive's compensation with the performance of our common stock. In addition, we also offer a cash incentive program. Various other benefits include medical, life insurance and retirement savings plans generally available to all of our employees.

#### *Elements of Executive Compensation*

##### *Base Salary*

Our policy is to set base salaries of our executives at industry averages, as determined using compensation surveys for our industry. We review base salaries of our executives on an annual basis and may adjust them in light of the executives' prior performance as well as independent compensation data for our industry. Base salaries for our executive officers for fiscal year 2001 were determined after considering the base salary level of our executive officers in prior years, and taking into account for each executive officer the amount of base salary as a component of total compensation.

##### *Cash Incentive Compensation*

In 2001, we implemented a cash incentive program for our executive officers. Due to our performance, however, we did not pay any cash incentives to any of our executive officers in 2001. We believe that a cash-based incentive plan is an appropriate means to provide our executive officers with competitive compensation. Cash bonuses are tied directly to our financial performance and the contribution of each executive to such performance. In order to determine such contribution, we review and evaluate the performance of the department or activity for which each executive has responsibility, the impact of that department or activity on our business and the skills and experience required for the job, coupled with a comparison of these elements with similar elements for other executives both inside and outside the Company.

##### *Stock Options*

In general, stock options are granted to our executive officers at the time of their hire and at such other times as we may deem appropriate. In reviewing option grants, we use the same industry survey data as used in our analysis of base salaries. We base our stock option award decisions upon a comparison with the equity ownership of officers holding similar positions in other medical technology companies, as well as upon the number of options and shares currently held by the executive and performance factors.

In granting stock options, it is our goal to align the interests of our management with those of our stockholders. In order to maintain the incentive aspects of these grants, we have determined that a significant percentage of any executive officer's stock options should be unvested option shares. Consistent with this determination, we generally grant options with a four-year vesting period and periodically review individual officer stock option holdings. We also issue stock options to lower the overall cash cost of compensation to us.

*Benefits*

We provide medical, life insurance and retirement savings benefits to our executive officers on terms generally available to all of our employees.

*Chief Executive Officer Compensation*

From January 1, 2001 through December 31, 2001, we paid Dr. Paul R. Sohmer, our President and Chief Executive Officer, a base salary of \$382,212. We did not grant to Dr. Sohmer any options as part of his 2001 compensation. However, in January 2001, we granted to Dr. Sohmer options to purchase 443,000 shares of common stock which were intended to be part of Dr. Sohmer's overall 2000 compensation, and therefore, were reported in our proxy statement for the 2001 Annual Meeting of Stockholders.

*Deduction Limit for Executive Compensation*

Section 162(m) of the Internal Revenue Code (the "Code") limits the tax deductibility by a public company of compensation in excess of one million dollars paid to any of its five most highly compensated executive officers. Outstanding stock options granted under our Equity Incentive Plan will not be subject to the limitation under applicable regulations. Our Compensation Committee intends to use its best efforts to structure future compensation so that executive compensation paid by us is fully deductible in accordance with Section 162(m) of the Code. Our Compensation Committee may, however, in a particular case, approve compensation that may not be deductible under Section 162(m).

By the Compensation Committee,

**Thomas A. Bonfiglio, M.D.**

**Robert E. Curry, Ph.D.**

## SUMMARY COMPENSATION TABLE

The following table sets forth certain compensation information for the year ended December 31, 2001 for:

- our Chief Executive Officer;
- our four most highly compensated executive officers whose total salary exceeded \$100,000; and
- one additional individual for whom disclosure would have been required but for the fact that he was not serving as an executive officer at December 31, 2001 (together, the "Named Executive Officers").

<u>Name and Principal Position</u>	<u>Year</u>	<u>Annual Compensation</u>		<u>Long-Term Compensation Awards</u>	<u>All Other Compensation (2)</u>
		<u>Salary</u>	<u>Bonus</u>	<u>Securities Underlying Options (#) (1)</u>	
Paul R. Sohmer, M.D. .... President and Chief Executive Officer	2001	\$382,212	—	—(4)	—
	2000	\$183,217(3)	\$125,000	893,000(4)	—
Thomas Gahm, Ph.D. .... Vice President of Computer Science	2001	\$194,352	—	40,000	\$5,250
	2000	\$181,577	—	9,948	\$5,447
	1999	\$175,657	—	34,209	\$2,006
David H. Robison .... Vice President of Operations	2001	\$175,373(5)	—	40,000	\$5,161
	2000	\$170,027	—	44,244	\$5,043
	1999	\$170,240	—	43,578	—
Mary K. Norton .... Vice President of Regulatory/ Government Affairs and Quality Assurance	2001	\$153,846	—	40,000	\$4,615
	2000	\$146,269	—	41,945	\$4,388
	1999	\$123,157	—	37,959	—
Ray W. Swanson, Jr. .... Senior Vice President of Commercial Operations(6)	2001	\$134,615	—	100,000	\$60,711(7)
Roger W. Martin .... Vice President of Sales and Marketing(8)	2001	\$151,264(9)	—	65,000	\$74,776(10)
	2000	\$141,534	—	9,063	\$1,872
	1999	\$8,238(11)	—	75,000	—

(1) Refer to the table "Option Grants in the Last Fiscal Year" below for details concerning the terms of the options granted during 2001.

(2) Represents contributions by us to our 401(k) plan on behalf of the Named Executive Officers.

(3) Dr. Sohmer joined us in June 2000. This number represents a portion of Dr. Sohmer's \$350,000 annual base salary that we paid to him from June 2000 until the end of 2000.

- (4) We did not grant to Dr. Sohmer any options as part of his 2001 compensation. However, in January 2001, we granted to Dr. Sohmer options to purchase 443,000 shares of common stock which were intended to be part of Dr. Sohmer's overall 2000 compensation, and therefore, were reported in our proxy statement for the 2001 Annual Meeting of Stockholders.
- (5) Mr. Robison served as our Vice President of Operations until December 31, 2001.
- (6) Ray W. Swanson, Jr. has served as our Senior Vice President of Commercial Operations since May, 2001.
- (7) Includes \$55,461 representing a relocation expense payment we made to Mr. Swanson.
- (8) Mr. Martin served as our Vice President of Sales and Marketing until July 2001.
- (9) Includes \$46,350 we paid in severance payments and \$10,963 we paid in accrued vacation pay to Mr. Martin from July 2001 until the end of the year. We paid these amounts to Mr. Martin pursuant to a severance arrangement made at the time of Mr. Martin's departure.
- (10) Includes \$69,526 we paid Mr. Martin under the terms of a non-compete agreement.
- (11) Mr. Martin joined us as our Vice President of Sales and Marketing in December 1999.

#### OPTION GRANTS IN LAST FISCAL YEAR

The following table sets forth certain information regarding options that we granted during the fiscal year ended December 31, 2001 to our Named Executive Officers.

Name	Number of Securities Underlying Options Granted (2)	Percent of Total Options Granted to Employees in Fiscal Year	Exercise Price Per Share	Expiration Date	Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term	
					5%(1)	10%(1)
Paul R. Sohmer, M.D. ...	—	—	—	—	—	—
Thomas Gahm, Ph.D. ...	40,000	5.49%	\$10.9375	01/24/11	\$53,123	\$343,735
David H. Robison .....	40,000	5.49%	\$10.9375	01/31/03(3)	\$0	\$0
Mary K. Norton .....	40,000	5.49%	\$10.9375	01/24/11	\$53,123	\$343,735
Ray W. Swanson, Jr. ....	100,000(4)	13.74%	\$5.46	04/29/11	\$657,808	\$1,384,338
Roger W. Martin .....	40,000	5.49%	\$10.9375	08/31/02(5)	\$0	\$0
	25,000	3.43%	\$10.9375	08/31/02(5)	\$0	\$0

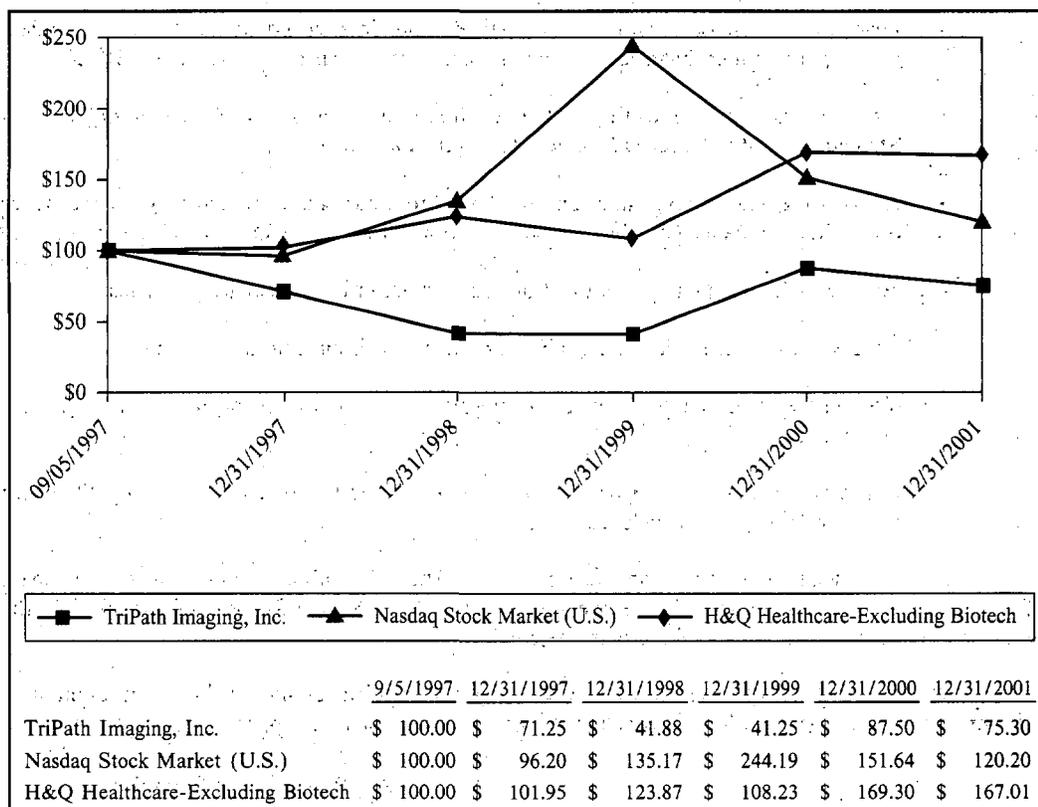
- (1) The dollar amounts shown in these columns are the result of calculations at the 5% and 10% rates required by the SEC and, therefore, are not intended to forecast possible future appreciation, if any, in the price of the underlying common stock. No gain to the optionee is possible without an increase in price of the underlying common stock, which will benefit all stockholders proportionately.

- (2) Unless otherwise noted, we granted these options on January 24, 2001. They become exercisable as to 1/48th of the shares on the first day of each month following the date of grant.
- (3) These options expire in 2003 due to the option holders' termination of employment with us in 2002. Under the terms of the option, if we terminate the option holder as an employee or consultant for any reason other than for cause, then the option holder has the right to exercise his options within 12 months from the date of termination.
- (4) We granted these options on April 29, 2001. They become exercisable as to 1/48th of the shares on the first day of each month following the date of grant.
- (5) These options expire in 2002 due to the option holders' termination of employment with us in 2001. Under the terms of the option, if we terminate the option holder as an employee or consultant for any reason other than for cause, then the option holder has the right to exercise his options within 12 months from the date of termination.

### Comparative Stock Performance Graph

The following graph shows the cumulative stockholder return of our common stock from September 5, 1997 (the first trading day for our common stock) through December 31, 2001 as compared with that of the Nasdaq (U.S. Companies) Index and the Hambrecht & Quist Healthcare Section Excluding Biotech Index. The total stockholder return is measured by dividing the per share price change of the respective securities, plus dividends, if any, for each fiscal year shown by the share price at the end of the particular fiscal year. The graph assumes the investment of \$100 in our common stock and each of the comparison groups on September 5, 1997 and assumes the reinvestment of dividends. We have never declared a dividend on our common stock. The stock price performance depicted in the graph below is not necessarily indicative of future price performance.

**Comparison of Cumulative Total Return Among TriPath Imaging, Inc., Nasdaq (U.S. Companies) Index and Hambrecht & Quist Healthcare Section-Excluding Biotech Index**



**COMPENSATION COMMITTEE INTERLOCKS,  
INSIDER PARTICIPATION AND CERTAIN TRANSACTIONS**

Our Compensation Committee consists of Drs. Bonfiglio and Curry, neither of whom is an executive officer. Dr. Curry is a consultant to DLJ Capital Corporation ("DLJ Capital"), a wholly-owned subsidiary of Credit Suisse First Boston (USA), Inc. DLJ Capital is the managing general partner of Sprout Capital VII, L.P. and Sprout CEO Fund, L.P., and acts as attorney-in-fact with respect to DLJ Capital's direct and indirect investments in us. Together, these entities are one of our principal stockholders.

**REPORT OF THE AUDIT COMMITTEE**

In the course of its oversight of our financial reporting process, the Audit Committee of our Board of Directors has:

- reviewed and discussed with our management and Ernst & Young LLP, our independent auditor, our audited financial statements for the fiscal year ended December 31, 2001;
- discussed with our auditor the matters required to be discussed by Statement on Auditing Standards No. 61, *Communication with Audit Committees*;
- received the written disclosures and the letter from our auditor required by Independence Standards Board Standard No. 1, *Independence Discussions with Audit Committees*;
- reviewed with our management and our auditor our critical accounting policies;
- discussed with our auditor the quality and adequacy of our internal controls;
- discussed with our auditor any relationships that may impact its objectivity and independence; and
- considered whether the provision of non-audit services by our auditor is compatible with maintaining their independence.

Based on the foregoing review and discussions, our Audit Committee recommended to our Board of Directors that the audited financial statements be included in our Annual Report on Form 10-K for the year ended December 31, 2001 for filing with the SEC.

Our Audit Committee has also reviewed and recommended revision of the Audit Committee Charter, the current form of which is attached to this proxy statement as Appendix A.

By the Audit Committee,

**Haywood D. Cochrane, Jr.**  
**Richard A. Charpie, Ph.D.**  
**David A. Thompson**

## SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Securities Exchange Act of 1934 requires that our directors, our executive officers and persons who own beneficially more than 10% of our common stock file initial reports of ownership and changes in ownership of our securities with the SEC. Section 16(a) also requires these individuals to furnish us with copies of all Section 16(a) reports that they file.

To our knowledge, based solely on a review of the copies of reports furnished to us and written representations that no other reports were required, we believe that during our 2001 fiscal year, our directors, executive officers, and 10% beneficial owners complied with all applicable Section 16(a) filing requirements, except that (1) one report covering one transaction was not filed as required on behalf of Richard A. Charpie in 2001, but the transaction was later reported on a Form 5 in February 2002, (2) one report covering one transaction was not filed as required in 2001 on behalf of Ms. Norton, but the transaction was later reported on a Form 4 in April 2001, and (3) one report covering one transaction was not filed as required in 2001 on behalf of Mr. Robison, but the transaction was later reported on a Form 4 in April 2001.

## INFORMATION CONCERNING AUDITORS

The firm of Ernst & Young LLP, independent accountants, has audited our accounts since our inception and will do so for 2002. Our Board of Directors has appointed Ernst & Young LLP to serve as our independent auditors for the fiscal year ending December 31, 2002. Representatives of Ernst & Young LLP are expected to attend the annual meeting to respond to appropriate questions, and will have the opportunity to make a statement if they desire.

The fees for services provided by Ernst & Young LLP to us in 2001 were as follows:

Audit Fees	\$121,745
All Other Services	\$ 85,940

## STOCKHOLDER PROPOSALS FOR THE 2003 ANNUAL MEETING

In order to be considered for inclusion in our proxy materials for the 2003 Annual Meeting of Stockholders, we must receive stockholder nominations of persons for election to our Board of Directors and proposals of business to be considered by our stockholders no later than December 25, 2002. Proposals should be sent to the attention of our Assistant Secretary at our offices at 780 Plantation Drive, Burlington, North Carolina 27215.

## ADVANCE NOTICE PROVISIONS FOR STOCKHOLDER PROPOSALS AND NOMINATIONS

Our by-laws provide that in order for a stockholder to bring business before, or propose director nominations at an annual meeting, the stockholder must give written notice to our Assistant Secretary not less than 50 days nor more than 75 days prior to the meeting. The notice must contain specified information about the proposed business or each nominee and the stockholder making the proposal or nomination. Assuming that the 2003 Annual Meeting of Stockholders is to be held on May 23, 2003, notice of stockholder proposals must be received no earlier than March 9, 2003, and no later than April 5, 2003. However, if we give our stockholders less than 65 days notice or prior public disclosure of the date of

the annual meeting, the notice given by the stockholder must be received by us not later than the 15th day following the day on which the notice of such annual meeting date was mailed or public disclosure made, whichever first occurs.

#### **OTHER MATTERS**

Copies of our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 as filed with the SEC are available to stockholders upon written request addressed to our Assistant Secretary at our offices at 780 Plantation Drive, Burlington, North Carolina 27215.

**TRIPATH IMAGING, INC.**  
**Audit Committee Charter**

***Purpose***

The principal purpose of the Audit Committee is to assist the Board of Directors in fulfilling its responsibility to oversee management's conduct of the Company's financial reporting process, including by reviewing the financial reports and other financial information provided by the Company, the Company's systems of internal accounting and financial controls, and the annual independent audit process.

In discharging its oversight role, the Committee is granted the power to investigate any matter brought to its attention with full access to all books, records, facilities and personnel of the Company and the power to retain outside counsel, auditors or other experts for this purpose. The outside auditor is ultimately accountable to the Board and the Committee, as representatives of the stockholders. The Board and the Committee shall have the ultimate authority and responsibility to select, evaluate and, where appropriate, replace the outside auditor. The Committee shall be responsible for overseeing the independence of the outside auditor.

This Charter shall be reviewed for adequacy on an annual basis by the Board.

***Membership***

The Committee shall be comprised of not less than three members of the Board, and the Committee's composition will meet the requirements of the Nasdaq Audit Committee Requirements. Accordingly, all of the members will be directors:

- Who have no relationship to the Company that may interfere with the exercise of their independence from management and the Company; and
- Who are financially literate or who become financially literate within a reasonable period of time after appointment to the Committee.

In addition, at least one member of the Committee will have accounting or related financial management expertise.

***Key Responsibilities***

The Committee's role is one of oversight, and it is recognized that the Company's management is responsible for preparing the Company's financial statements and that the outside auditor is responsible for auditing those financial statements.

The following functions shall be the common recurring activities of the Committee in carrying out its oversight role. The functions are set forth as a guide and may be varied from time to time as appropriate under the circumstances.

- The Committee shall review with management and the outside auditor the audited financial statements to be included in the Company's Annual Report on Form 10-K and the Annual

Report to Stockholders, and shall review and consider with the outside auditor the matters required to be discussed by Statement on Auditing Standards No. 61.

- As a whole, or through the Committee chair, the Committee shall review with the outside auditor, prior to filing with the SEC, the Company's interim financial information to be included in the Company's Quarterly Reports on Form 10-Q and the matters required to be discussed by SAS No. 61.
- The Committee shall periodically discuss with management and the outside auditor the quality and adequacy of the Company's internal controls and internal auditing procedures and discuss with the outside auditor how the Company's financial systems and controls compare with best practices of the industry.
- The Committee shall periodically review with management and the outside auditor the quality, as well as the acceptability, of the Company's accounting policies and discuss with the outside auditor how the Company's financial systems and controls compare with best practices of the industry.
- The Committee shall review with management and the outside auditor the Company's accounting policies, which may be viewed as critical.
- The Committee shall request from the outside auditor annually a formal written statement delineating all relationships between the auditor and the Company consistent with Independence Standards Board Standard No. 1, discuss with the outside auditor any such disclosed relationships and their impact on the outside auditor's independence, and take or recommend that the Board take appropriate action regarding the independence of the outside auditor.
- The Committee shall be consulted regarding retention of the outside auditor to perform any significant non-audit services for the Company and the effect of such retention on the outside auditor's independence.
- The Committee, subject to any action that may be taken by the Board, shall have the ultimate authority and responsibility to select (or nominate for stockholder approval), evaluate and, where appropriate, replace the outside auditor.
- The Committee shall review with management and the outside auditor any material financial or other arrangements of the Company which do not appear on the Company's financial statements and any transactions or courses of dealing with third parties that are significant in size or involve terms or other aspects that differ from those that would likely be negotiated with independent parties and which arrangements or transactions are relevant to an understanding of the Company's financial statements.
- Any issue of significant financial misconduct shall be brought to the attention of the Committee for its consideration.

The Committee shall report to the Board whether, based on the foregoing reviews and discussions, the Committee recommends that the financial statements be included in the Company's Annual Report on Form 10-K.

TRIPATH IMAGING, INC.

AMENDED AND RESTATED  
1996 EQUITY INCENTIVE PLAN

1. Purpose.

The purpose of the TriPath Imaging, Inc. 1996 Amended and Restated Equity Incentive Plan (the "Plan") is to attract and retain key personnel of the Company and its Affiliates, to provide an incentive for them to achieve long-range performance goals, and to enable them to participate in the long-term growth of the Company by granting Awards with respect to the Company's Common Stock.

2. Administration.

The Plan shall be administered by the Committee, provided that the Board may in any instance perform any of the functions delegated to the Committee hereunder. The Committee shall select the Participants to receive Awards and shall determine the terms and conditions of the Awards. The Committee shall have authority to adopt, alter and repeal such administrative rules, guidelines and practices governing the operation of the Plan as it shall from time to time consider advisable, and to interpret the provisions of the Plan. The Committee's decisions shall be final and binding. To the extent permitted by applicable law, the Committee may delegate to one or more executive officers of the Company the power to make Awards to Participants who are not Reporting Persons or Covered Employees and all determinations under the Plan with respect thereto, provided that the Committee shall fix the maximum amount of such Awards for all such Participants and a maximum for any one Participant.

3. Eligibility.

All employees, directors and consultants of the Company or any Affiliate capable of contributing significantly to the successful performance of the Company, other than a person who has irrevocably elected not to be eligible, are eligible to be Participants in the Plan. Incentive Stock Options may be granted only to persons eligible to receive such Options under the Code.

4. Stock Available for Awards.

(a) *Amount.* Subject to adjustment under subsection (b), Awards may be made under the Plan for up to 6,296,325 shares of Common Stock. If any Award expires or is terminated unexercised or is forfeited or settled in a manner that results in fewer shares outstanding than were awarded, the shares subject to such Award, to the extent of such expiration, termination, forfeiture or decrease, shall again be available for award under the Plan. Common Stock issued through the assumption or substitution of outstanding grants from an acquired company shall not reduce the shares available for Awards under the Plan. Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares.

(b) *Adjustment.* In the event that the Committee determines that any stock dividend, extraordinary cash dividend, recapitalization, reorganization, merger, consolidation, split-up, spin-off,

combination, exchange of shares or other transaction affects the Common Stock such that an adjustment is required in order to preserve the benefits intended to be provided by the Plan, then the Committee (subject in the case of Incentive Stock Options to any limitation required under the Code) shall equitably adjust any or all of (i) the number and kind of shares in respect of which Awards may be made under the Plan, (ii) the number and kind of shares subject to outstanding Awards, (iii) the exercise price with respect to any of the foregoing, and (iv) if considered appropriate, the Committee may make provision for a cash payment with respect to an outstanding Award; provided that in the case (i) or (ii) above the number of shares subject to any Award shall always be a whole number.

(c) *Limit on Individual Grants.* The maximum number of shares of Common Stock subject to Options and Stock Appreciation Rights that may be granted to any Participant in the aggregate in any calendar year shall not exceed 1,000,000 shares, subject to adjustment under subsection (b).

5. Stock Options.

(a) *Grant of Options.* Subject to the provisions of the Plan, the Committee may grant options ("Options") to purchase shares of Common Stock complying with the requirements of Section 422 of the Code or any successor provision and any regulations thereunder ("Incentive Stock Options") and (ii) not intended to comply with such requirements ("Nonstatutory Stock Options"). The Committee shall determine the number of shares subject to each Option and the exercise price therefor, which in the case of Incentive Stock Options shall not be less than 100% of the Fair Market Value of the Common Stock on the date of grant. No Incentive Stock Option may be granted hereunder more than ten years after the effective date of the Plan.

(b) *Terms and Conditions.* Each Option shall be exercisable at such times and subject to such terms and conditions as the Committee may specify in the applicable grant or thereafter. The Committee may impose such conditions with respect to the exercise of Options, including conditions relating to applicable federal or state securities laws, as it considers necessary or advisable.

(c) *Payment.* Payment for shares to be delivered pursuant to any exercise of an Option may be made in whole or in part in cash or, to the extent permitted by the Committee at or after the grant of the Option, by delivery of a note or other commitment satisfactory to the Committee or shares of Common Stock owned by the optionee, including Restricted Stock, or by retaining shares otherwise issuable pursuant to the Option, in each case valued at their Fair Market Value on the date of delivery or retention, or such other lawful consideration as the Committee may determine.

6. Stock Appreciation Rights.

(a) *Grant of SARs.* Subject to the provisions of the Plan, the Committee may grant rights to receive any excess in value of shares of Common Stock over the exercise price ("Stock Appreciation Rights" or "SARs") in tandem with an Option (at or after the award of the Option), or alone and unrelated to an Option. SARs in tandem with an Option shall terminate to the extent that the related Option is exercised, and the related Option shall terminate to the extent that the tandem SARs are exercised. The Committee shall determine at the time of grant or thereafter whether SARs are settled in cash, Common Stock or other securities of the Company, Awards or other property, and may define the manner of determining the excess in value of the shares of Common Stock.

(b) *Exercise Price.* The Committee shall fix the exercise price of each SAR or specify the manner in which the price shall be determined. An SAR granted in tandem with an Option shall have an exercise price not less than the exercise price of the related Option. An SAR granted alone and unrelated to an Option may not have an exercise price less than 100% of the Fair Market Value of the Common Stock on the date of the grant, provided that such an SAR granted to a new employee or consultant within 90 days of the date of employment may have a lower exercise price so long as it is not less than 100% of Fair Market Value on the date of employment.

7. Restricted Stock.

(a) *Grant of Restricted Stock.* Subject to the provisions of the Plan, the Committee may grant shares of Common Stock subject to forfeiture ("Restricted Stock") and determine the duration of the period (the "Restricted Period") during which, and the conditions under which, the shares may be forfeited to the Company and the other terms and conditions of such Awards. Shares of Restricted Stock may be issued for no cash consideration, such minimum consideration as may be required by applicable law or such other consideration as the Committee may determine.

(b) *Restrictions.* Shares of Restricted Stock may not be sold, assigned, transferred, pledged or otherwise encumbered, except as permitted by the Committee, during the Restricted Period. Notwithstanding the foregoing, in the Committee's discretion, Awards in the form of Restricted Stock may be made transferable to a limited liability corporation controlled solely by the Participant. Shares of Restricted Stock shall be evidenced in such manner as the Committee may determine. Any certificates issued in respect of shares of Restricted Stock shall be registered in the name of the Participant and unless otherwise determined by the Committee, deposited by the Participant, together with a stock power endorsed in blank, with the Company. At the expiration of the Restricted Period, the Company shall deliver such certificates to the Participant or if the Participant has died, to the Participant's Designated Beneficiary.

8. General Provisions Applicable to Awards.

(a) *Reporting Person Limitations.* Notwithstanding any other provision of the Plan, Awards made to a Reporting Person shall not be transferable by such person other than by will or the laws of descent and distribution and are exercisable during such person's lifetime only by such person or by such person's guardian or legal representative. Awards, unless Incentive Stock Options, may also be made transferable pursuant to a domestic relations order as defined in the Code or Title I of the Employee Retirement Income Security Act or the rules thereunder.

(b) *Documentation.* Each Award under the Plan shall be evidenced by a writing delivered to the Participant specifying the terms and conditions thereof and containing such other terms and conditions not inconsistent with the provisions of the Plan as the Committee considers necessary or advisable to achieve the purposes of the Plan or to comply with applicable tax and regulatory laws and accounting principles.

(c) *Committee Discretion.* Each type of Award may be made alone, in addition to or in relation to any other Award. The terms of each type of Award need not be identical, and the Committee need not treat Participants uniformly. Except as otherwise provided by the Plan or a particular Award, any determination with respect to an Award may be made by the Committee at the time of grant or at any time thereafter.

(d) *Dividends and Cash Awards.* In the discretion of the Committee, any Award under the Plan may provide the Participant with (i) dividends or dividend equivalents payable currently or deferred with or without interest and (ii) cash payments in lieu of or in addition to an Award.

(e) *Termination of Employment.* The Committee shall determine the effect on an Award of the disability, death, retirement or other termination of employment of a Participant and the extent to which, and the period during which, the Participant's legal representative, guardian or Designated Beneficiary may receive payment of an Award or exercise rights thereunder.

(f) *Change in Control.* In order to preserve a Participant's rights under an Award in the event of a "change in control" (as defined by the Committee) of the Company, the Committee in its discretion may, at the time an Award is made or at any time thereafter, take one or more of the following actions: (i) provide for the acceleration of any time period relating to the exercise or payment of the Award, (ii) provide for payment to the Participant of cash or other property with a Fair Market Value equal to the amount that would have been received upon the exercise or payment of the Award had the Award been exercised or paid upon the change in control, (iii) adjust the terms of the Award in a manner determined by the Committee to reflect the change in control, (iv) cause the Award to be assumed, or new rights substituted therefor, by another entity, or (v) make such other provision as the Committee may consider equitable to Participants and in the best interests of the Company.

(g) *Loans.* The Committee may authorize the making of loans or cash payments to Participants in connection with the grant or exercise of any Award under the Plan, which loans may be secured by any security, including Common Stock, underlying or related to such Award (provided that the loan shall not exceed the Fair Market Value of the security subject to such Award), and which may be forgiven upon such terms and conditions as the Committee may establish at the time of such loan or at any time thereafter.

(h) *Withholding Taxes.* The Participant shall pay to the Company, or make provision satisfactory to the Committee for payment of, any taxes required by law to be withheld in respect of Awards under the Plan no later than the date of the event creating the tax liability. In the Committee's discretion, such tax obligations may be paid in whole or in part in shares of Common Stock, including shares retained from the Award creating the tax obligation, valued at their Fair Market Value on the date of delivery. The Company and its Affiliates may, to the extent permitted by law, deduct any such tax obligations from any payment of any kind otherwise due to the Participant.

(i) *Foreign Nationals.* Awards may be made to Participants who are foreign nationals or employed outside the United States on such terms and conditions different from those specified in the Plan as the Committee considers necessary or advisable to achieve the purposes of the Plan or to comply with applicable laws.

(j) *Amendment of Award.* The Committee may amend, modify or terminate any outstanding Award, including substituting therefor another Award of the same or a different type, changing the date of exercise or realization and converting an Incentive Stock Option to a Nonstatutory Stock Option, provided that no award may be modified, repriced, replaced or regranted through cancellation without shareholder approval (except in connection with a change in the Company's capitalization), if the effect of such modification or cancellation would be to reduce the exercise price for the shares underlying such award, and, provided, further, that any such action shall require the Participant's consent unless:

(i) in the case of a termination of, or a reduction in the number of shares issuable under, an Option, any time period relating to the exercise of such Option or the eliminated portion, as the case may be, is waived or accelerated before such termination or reduction (and in such case the

Committee may provide for the Participant to receive cash or other property equal to the net value that would have been received upon exercise of the terminated Option or the eliminated portion, as the case may be); or

(ii) in any other case, the Committee determines that the action, taking into account any related action, would not materially and adversely affect the Participant.

9. Certain Definitions.

"Affiliate" means any business entity in which the Company owns directly or indirectly 50% or more of the total voting power or has a significant financial interest as determined by the Committee.

"Award" means any Option, Stock Appreciation Right or Restricted Stock granted under the Plan.

"Board" means the Board of Directors of the Company.

"Code" means the Internal Revenue Code of 1986, as amended from time to time, or any successor law.

"Committee" means one or more committees each comprised of not less than two members of the Board appointed by the Board to administer the Plan or a specified portion thereof. If the Committee is authorized to grant Options to a Reporting Person or a Covered Employee, each member shall be a "Non-Employee Director" or the equivalent within the meaning of Rule 16b-3 under the Exchange Act or an "outside director" or the equivalent within the meaning of Section 162(m) of the Code, respectively. In the event no such Committee is appointed, then "Committee" means the Board.

"Common Stock" means the Common Stock, \$0.01 par value, of the Company.

"Company" means TriPath Imaging, Inc., a Delaware corporation.

"Covered Employee" means a person whose income is subject to Section 162(m) of the Code.

"Designated Beneficiary" means the beneficiary designated by a Participant, in a manner determined by the Committee, to receive amounts due or exercise rights of the Participant in the event of the Participant's death. In the absence of an effective designation by a Participant, "Designated Beneficiary" means the Participant's estate.

"Exchange Act" means the Securities Exchange Act of 1934, as amended from time to time, or any successor law.

"Fair Market Value" means, with respect to the Common Stock or any other property, the fair market value of such property as determined by the Committee in good faith or in the manner established by the Committee from time to time.

"Participant" means a person selected by the Committee to receive an Award under the Plan.

"Reporting Person" means a person subject to Section 16 of the Exchange Act.

10. Miscellaneous.

(a) *No Right To Employment.* No person shall have any claim or right to be granted an Award. Neither the Plan nor any Award hereunder shall be deemed to give any employee the right to continued employment or to limit the right of the Company to discharge any employee at any time.

(b) *No Rights As Stockholder.* Subject to the provisions of the applicable Award, no Participant or Designated Beneficiary shall have any rights as a stockholder with respect to any shares of Common Stock to be distributed under the Plan until he or she becomes the holder thereof. A Participant to whom Common Stock is awarded shall be considered the holder of the Stock at the time of the Award except as otherwise provided in the applicable Award.

(c) *Effective Date.* This Amended and Restated 1996 Equity Incentive Plan became effective on June 26, 1997.

(d) *Amendment of Plan.* The Board may amend, suspend or terminate the Plan or any portion thereof at any time, subject to such stockholder approval as the Board determines to be necessary or advisable to comply with any tax or regulatory requirement.

(e) *Governing Law.* The provisions of the Plan shall be governed by and interpreted in accordance with the laws of Delaware.

\*\*\*\*\*

*This Plan was approved by the Board of Directors on November 22, 1996.*

*This Plan was amended by the Board of Directors on May 19, 1997.*

*This Plan, as amended, was approved by the stockholders on June 26, 1997.*

*This Plan was amended and restated by the Board of Directors on June 24, 1997.*

*This Plan, as amended and restated, was approved by the stockholders on June 26, 1997.*

*This Plan was amended by the Board of Directors on February 2, 1999.*

*This Plan, as amended, was approved by the stockholders on May 26, 1999.*

*This Plan, as amended, was approved by the stockholders on June 1, 2000.*

*This Plan was amended by the Board of Directors on January 15, 2002.*

*This Plan was amended by the Board of Directors on February 4, 2002.*

*This Plan was amended by the Board of Directors on April 22, 2002.*

*This Plan, as amended, was approved by the stockholders on . . . 2002.*

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**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

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**FORM 10-K**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2001

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

**Commission File Number: 0-22885**

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**TRIPATH IMAGING, INC.**

(exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**56-1995728**  
(I.R.S. Employer  
Identification Number)

**780 Plantation Drive, Burlington, North Carolina 27215**

(Address of principal executive offices including zip code)

**Registrant's telephone number, including area code: (336) 222-9707**

Securities registered pursuant to Section 12(b) of the Act:

**None**

Securities registered pursuant to Section 12(g) of the Act:

**Common Stock, \$0.01 Par Value**

(Title of each class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES  NO

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

The aggregate market value of voting stock held by non-affiliates of the registrant as of March 25, 2002 was: \$127,533,474.

There were 37,454,684 shares of the registrant's Common Stock outstanding as of March 25, 2002.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive proxy statement of the Registrant for the Registrant's 2002 Annual Meeting of Shareholders to be held on May 23, 2002, which definitive proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year of December 31, 2001, are incorporated by reference into Part III of this Form 10-K.

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## TriPath Imaging, Inc.

### Table of Contents

#### Part I.

Item 1.	Business .....	2
Item 2.	Properties .....	26
Item 3.	Legal Proceedings .....	26
Item 4.	Submission of Matters to a Vote of Security Holders .....	26

#### Part II.

Item 5.	Market for the Registrant's Common Equity and Related Stockholder Matters .....	27
Item 6.	Selected Consolidated Financial Data .....	28
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations .....	28
Item 7A.	Quantitative and Qualitative Disclosures About Market Risks .....	39
Item 8.	Consolidated Financial Statements and Supplementary Data .....	40
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure .....	40

#### Part III.

Item 10.	Directors and Executive Officers of the Registrant .....	40
Item 11.	Executive Compensation .....	40
Item 12.	Security Ownership of Certain Beneficial Owners and Management .....	40
Item 13.	Certain Relationships and Related Transactions .....	40

#### Part IV.

Item 14.	Exhibits, Consolidated Financial Statement Schedules and Reports on Form 8-K .....	40
Signatures .....		44

As used in this report, the terms "we," "us," "our," "TriPath Imaging" and the "Company" mean TriPath Imaging, Inc. and its subsidiaries, unless the context indicates another meaning.

#### *Note Regarding Trademarks*

AutoCyte®, AutoCyte Quic®, AutoPap®, CytoRich®, ImageTiter®, NeoPath®, PAPMAP®, and PREPAP® are registered trademarks of TriPath Imaging, Inc. TriPath Imaging™, TriPath Care Technologies™, i<sup>3</sup> Series™, FocalPoint™, PrepMate™, PrepStain™, SurePath™, SlideWizard™, AutoCyte PREP™ and PREPAP™, are trademarks of TriPath Imaging, Inc. All other products and company names are trademarks of their respective holders.

## PART I

### Item 1. Business

This Annual Report on Form 10-K contains forward-looking statements, including statements regarding our results of operations, research and development programs, clinical trials and collaborations. Statements that are not historical facts are based on our management's current expectations, beliefs, assumptions, estimates, forecasts and projections. These forward-looking statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that could cause actual results to differ significantly from those discussed in these forward-looking statements. Important factors that could cause or contribute to these differences include those described in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies" and in "Factors Affecting Future Operating Results" attached hereto as Exhibit 99.1 and incorporated by reference into this Form 10-K. You should not place undue reliance on the forward-looking statements, which speak only as the date of this report. We undertake no obligation to update these statements to reflect events or circumstances occurring after the date of this report or to reflect the occurrence of unanticipated events, except as required by law.

### The Company

We develop, manufacture, market, and sell proprietary products for cancer detection, diagnosis, staging, and treatment selection. We are using our proprietary technologies, and know-how to create an array of products designed to improve the clinical management of cancer. We were formed in September 1999 through the merger of AutoCyte, Inc. and NeoPath, Inc. and acquisition of the technology and intellectual property of Neuromedical Systems, Inc. We were created to leverage the complementary nature of the products, technologies, and intellectual property developed by our predecessor companies, all of whom were early pioneers in the application of computerized image processing and analysis to detect the often subtle cellular abnormalities associated with cancer and its precursors. To date, we have developed an integrated solution for cervical cancer screening and other products that deliver image management, data handling, and prognostic tools for cell diagnosis, cytopathology and histopathology. We believe that recent advances in genomics, biology, and informatics are providing new opportunities and applications for our proprietary technology.

We are organized into two operating units:

- Commercial Operations, through which we manage the market introduction, sales, service, manufacturing and ongoing development of our products; and
- TriPath Oncology, our wholly-owned subsidiary through which we manage the development of molecular diagnostic and pharmacogenomic tests for cancer.

### Commercial Operations

During 2002, we adopted the trademark TriPath Care Technologies to describe our commercial product offering and to communicate the broad nature of our corporate vision and the value created by our growing product portfolio, including the "*i*<sup>3</sup>" series and SlideWizard product lines.

To further refine our market positioning and to enhance brand awareness among our customers, we re-branded our cervical cancer screening products under the "*i*<sup>3</sup>" product line. Our "*i*<sup>3</sup>" series product line for screening for cervical cancer is the first integrated system for the collection, preparation, staining and computerized analysis of conventional Pap smears and liquid-based, thin-layer preparations. Our *i*<sup>3</sup> product line includes the:

- SurePath System, a proprietary, liquid-based cytology sample collection, preservation and transport system and PrepStain, an automated slide preparation system that produces slides with a standardized, thin layer of stained cervical cells, which together were formerly known as the AutoCyte PREP System ("PrepStain"). SurePath addresses errors in cell sample collection and slide preparation while providing a liquid medium for adjunctive laboratory testing of specimens, whereas the PrepStain slide

processor reduces the complexity of interpretation by providing a homogeneous, more representative and standardized thin-layer of stained cells and a liquid medium for adjunctive laboratory testing of specimens. The FDA approved PrepStain in June 1999.

- FocalPoint SlideProfiler System, a slide screening system that uses proprietary technology to distinguish between normal thin-layer or conventional Pap smears and those that have the highest likelihood of abnormality, formerly known as the AutoPap Primary Screening System ("FocalPoint"). In May 1998, FocalPoint was approved by the FDA as the first and only fully automated device for primary screening of conventional Pap smear slides. Additionally, in October 2001, the FocalPoint was approved by the FDA to process thin-layer slides prepared using our PrepStain system.

Our SlideWizard product line includes the Image Titer, an FDA cleared method for automating the measurement of antinuclear antibody, research applications for DNA, immunohistochemical quantification, cellular analysis, and expression quantification, a system for the transmission and interpretation of tissue specimens via remote telecommunications or "telepathology", and a software based storage and retrieval system for microscopic images.

### *TriPath Oncology*

Our TriPath Oncology business focuses on developing and commercializing molecular diagnostic and pharmacogenomic tests for a variety of cancers. On July 31, 2001, we entered into a series of agreements with Becton, Dickinson and Company ("BD") to develop and commercialize molecular diagnostics and pharmacogenomic tests for malignant melanoma and cancers of the cervix, breast, ovary, colon and prostate as part of the ongoing strategic alliance between BD and Millennium Pharmaceuticals, Inc. ("Millennium").

The goal of our molecular oncology program is to utilize discoveries in genomics and proteomics research to develop and commercialize diagnostic and pharmacogenomic tests to improve the clinical management of cancer. Specifically, we have active programs in development designed to identify individuals with cancer at the earliest possible stage of the disease, provide individualized predictive and prognostic information, guide treatment selection for patients with cancer, and predict disease recurrence. The core products and services we are developing through our collaboration with BD will be based upon genomic and proteomic markers identified through discovery research, conducted at Millennium, under its existing research and development agreement with BD. TriPath Oncology will clinically validate and develop these proprietary cancer markers into commercial diagnostic and pharmacogenomic oncology products and services. Commercial responsibilities for resulting products will be shared between BD and TriPath Oncology. BD will continue to fund additional discovery research activities at Millennium.

We believe that the successful development and commercialization of genomics based oncology products will require:

- identification and validation of novel molecular markers;
- expertise in assay formatting and development; and
- development of clinical instrumentation that will permit multiple and quantitative gene and protein expression analyses within cells.

Completion of these steps requires technology and expertise in gene discovery and proteomics, assay formatting and development, and image analysis and instrumentation. We believe that our proprietary assets and technologies in imaging analysis together with the broad access to novel molecular markers offered by our relationship with BD, will provide us with the necessary technology and expertise to successfully develop improved diagnostic oncology products. We also believe that the establishment of TriPath Oncology as a separate business unit will provide the flexibility necessary to create an organization and dedicated management team with top-notch skills and expertise in assay formatting and development, thereby fulfilling our vision for success in the molecular oncology diagnostics market.

## **The Cancer Market**

Cancer is a chronic and complex disease characterized by uncontrolled growth and spread of abnormal cells. According to the World Health Organization (WHO), the worldwide incidence of cancer in the year 2000 exceeded 10 million cases, excluding basal and squamous cell cancers of the skin. The WHO further estimates that approximately 6.2 million deaths worldwide were attributable to cancer in 2000. In the United States, the American Cancer Society (ACS) estimates that roughly 1.3 million cases of non-skin cancers were diagnosed in 2001. In the United States, men have about a 1 in 2 lifetime risk of developing cancer, and women have about a 1 in 3 risk. The most frequently diagnosed cancers include cancer of the prostate, breast, lung and colon, which combined account for just over one half of all non-skin cancers diagnosed in the United States.

Treatments for cancer are expensive and oftentimes ineffective. Current treatments for cancer include surgery, radiation, and chemotherapy. Surgery is limited in its effectiveness because it treats the tumor at a specific site and may not remove all the cancer cells, particularly if the cancer has spread. Radiation and chemotherapy can treat the cancer at multiple sites but can cause serious adverse side effects because they destroy healthy cells and tissues as well as cancer cells. The ACS projected that in 2001, approximately one half million Americans died of cancer-related illness and that the five year relative survival rate for individuals diagnosed with cancer is about 60%. The National Institutes of Health estimates that the overall costs of cancer-related illness in the US exceed \$180 billion in 2000.

The market for cancer diagnostics is expected to grow substantially due to the increased incidence of cancer, an aging population, early cancer awareness, pressure to reduce cancer mortality rates and improvements in healthcare screening systems. The existing cancer diagnostics market is characterized predominantly by tests or methods that identify the presence of surrogate markers or cellular abnormalities that are correlated with the presence or stage of disease but, for the most part, do little to provide information specific to the disease or the outcome of the patient. The current technologies used in cancer diagnostics consist primarily of tumor marker immunoassays, cytology evaluation and mammography.

While some of the underlying causes of specific cancers can be traced to a single genetic alteration, it is now believed that multiple complex genetic changes underlie the development of the vast majority of cancers. However, the identification of genetic anomalies alone is unlikely to prove clinically significant as many genetic events may have minimal or no impact on a patient's health, whereas others may pose life-threatening health risks. Determining the interrelationship of genes and proteins, and their interaction with one another will be as important as understanding the underlying cause of the genetic change itself. The scientific community's knowledge of these underlying genetic factors has only recently come about through the development of more sophisticated research and discovery tools, investment in mapping of the human genome, and development of bioinformatics capabilities to assess the clinical relevance of these genetic abnormalities.

In recent years, novel molecular oncology tests have been introduced to provide additional clinical information previously unavailable to assess an individual's predisposition or lifetime risk of developing certain cancers. These tests are also used to screen and assist in the diagnosis of the presence of disease, to assess patient prognosis and outcome more accurately, to guide therapeutic selection in the management of certain cancers and to monitor for disease recurrence. These tests offer the promise of providing a more accurate, disease-specific understanding of cancer to best address the needs of medical practitioners.

### *Cervical Cancer*

Cancer of the uterine cervix, or cervical cancer, is the second most common form of cancer among women worldwide, with approximately 500,000 new cases reported each year. The American Cancer Society estimates that during 2002, doctors will diagnose approximately 13,000 cases of invasive cervical cancer in the United States, and that approximately 4,100 women will die in the United States of cervical cancer in 2002.

Invasive cervical cancer spreads from the surface of the cervix to tissue deeper in the cervix or to other parts of the body. Cervical cancer develops in stages over a period of time beginning with pre-invasive changes that eventually progress to invasion. Because of the progression to invasion, most all deaths due to invasive

cervical cancer can be prevented with early-stage detection and treatment. Early detection is critical in promoting patient wellness. The more advanced the cancer, the lower the chances are of managing and/or curing the patient. Thus, regular cervical screening examinations are recommended in the United States and many foreign countries.

### *The Conventional Pap Smear*

The conventional Pap smear is currently the most widely used screening test for cervical cancer. This test was developed by Dr. George N. Papanicolaou in the 1940's and has essentially remained unchanged until the advent of liquid-based cytology and automated computer primary screening. The Pap smear detects pre-cancerous lesions before they invade the cervix while they are 100% curable. It is estimated that clinical laboratories in the United States perform over 50 million Pap smears annually. We believe that annual test volume outside of the United States is in excess of 80 million. Of the 50 million annual Pap smear tests performed in the United States, industry sources estimate that approximately 2.5 million, or five percent, are diagnosed at the pre-cancerous or cancer stage.

In the United States, although widespread and regular use of the conventional Pap smear has contributed to a greater than 70% decrease in deaths resulting from cervical cancer, the death rate from the disease has declined at a rate of only approximately 1.6% per year. We believe that despite the success of the conventional Pap smear as a diagnostic tool, there are practical limitations to the this test which contribute to an estimated \$5.0 billion in annual costs. These costs are associated with the treatment of advanced pre-cancerous and cancerous cervical disease. Additional costs are also incurred by third-party payers due to repeat testing for poor quality smears and by clinical laboratories due to litigation associated with inaccurate diagnoses. The introduction of liquid-based cytology has improved specimen adequacy and automated computer screening has improved diagnostic accuracy.

The evaluation of conventional Pap smears involves the science of cytology, which includes the microscopic evaluation and interpretation of pre-cancerous and malignant morphological changes in cells. The process begins with the collection of cervical cells during a gynecologic pelvic examination. To obtain a Pap smear, a clinician uses a sampling device to scrape the surface of a woman's uterine cervix to collect a sample of cervical cells. If the conventional Pap smear method is used, this sample is smeared onto a microscope slide and the sampling device is discarded. If our SurePath liquid-based method is used, the device is placed into our proprietary fluid and the cells are suspended in the fluid media.

After the cervical sample is taken, the sample and patient information are sent to a clinical laboratory for further processing, screening and diagnosis. A cytotechnologist who is specially trained to evaluate cell changes screens and interprets the slide. Any abnormality is further reviewed by a medical doctor or pathologist.

Typically, about 90% to 95% of all Pap smears are classified as normal. Pap smears classified as other than normal specify the degree of abnormal change. For example atypical cells commonly referred to as "atypia," represents the least significant change with a very low likelihood to progress to cancer if left untreated. The next classification is low-grade squamous intraepithelial lesions ("LSIL") which has a slightly higher likelihood of progressing to cancer if left untreated but overall is still relatively low. High-grade squamous intraepithelial lesions ("HSIL") represent changes that biologically have the highest likelihood of progressing to cancer if left untreated. The most serious classification is the diagnosis of cancer itself. Optimally, the Pap test's objective is to detect the atypical to HSIL lesions as well as early invasive cancer so the lesion can be treated and the patient cured.

### *Limitations of the Conventional Pap Smear Test Process*

Each Pap smear slide sample typically contains 50,000 to 300,000 cervical cells. The process of manually screening and interpreting a conventional Pap smear requires intense visual examination of the slide sample through a microscope. Because abnormal cells are not readily visible, errors may occur and abnormal cells may not be seen by the cytotechnologist during the microscopic review process. Abnormal cells can be obscured by blood, mucous or white blood cells making them difficult to find and interpret. Other factors such

as air-drying distorts the cells, resulting in normal cells being misinterpreted as abnormal, or abnormal cells being misinterpreted as normal. Most of these limitations are a result of poor specimen quality and have been shown to be minimized by using a liquid-based collection method

Pap smears also have a highly variable false-negative rate. A false-negative results when the patient actually has evidence of disease but the Pap smear is reported as negative. False-negative rates of the conventional Pap smear vary widely among laboratories and have been reported to range from 5% to 55%, depending on factors such as the skill and experience of the practitioner who collects the sample and prepares the slide, and the level of training of the cytotechnologist and pathologist who review the slide. Studies suggest that the highest percentage of false negative diagnoses are the result of inadequacies in sample collection and slide preparation. In this situation, the abnormal cells are either not collected properly on the sampling device or are collected properly on the sampling device but are not transferred properly to the microscopic glass slide. Other causes of false-negatives are attributable to detection and interpretation errors where abnormal cells are present on the Pap smear but they are either not seen at all, or are seen but interpreted as negative.

A study published in the American Journal of Clinical Pathology reported that, with a conventional Pap smear, as much as 80% of the sample taken from a patient may not be transferred to the slide and remains on the discarded collection device. In addition to inadequate cell transfer, the conventional Pap smear slide preparation process may produce inconsistent and non-uniform slides with extreme variability in quality, often making examination difficult. If a Pap smear is interpreted as unsatisfactory or less-than-optimal because of poor quality sampling or because of obscuring factors, the clinician may be prompted to call the patient back for a repeat test.

When using the conventional Pap smear process, a physician is unable to perform additional testing using the original patient sample. If additional testing is required, the patient must return to the physician's office to provide a second sample. This can cause a great deal of stress to the patient, thereby reducing the accuracy of the second sample. The SurePath liquid collection method allows the laboratory access to the remaining cellular material from the original patient sample. Repeat and ancillary testing from the residual cell solution may provide a more cost effective patient management program for inconclusive Pap smear tests, and may reduce a patient's stress and anxiety associated with repeat testing.

## **Our Products**

### **The *i*<sup>3</sup> Series Product Line**

Our "*i*<sup>3</sup>" series product line of cervical cytology products are intended to address the current limitations of the conventional Pap smear process and the lack of automation in the cytopathology laboratory. The products within our "*i*<sup>3</sup>" series product line work together as part of an integrated system for the collection, preparation, staining and computerized analysis of liquid-based, thin-layer Pap preparations and the screening of conventional Pap smears. The silent exponent "3" suggests the expertise contributed by each of our three predecessor companies, AutoCyte, NeoPath and NSI, as well as the value of these component products in providing intelligent identification through innovation. Within the "*i*<sup>3</sup>" series line, individual products have been renamed to better communicate the value they provide to the physician, patients and laboratory professionals. Our "*i*<sup>3</sup>" series line of cervical cytology products includes SurePath, formerly called CytoRich, a proprietary, liquid-based cytology sample collection, cell preservation and transport system, and PrepStain, an automated slide preparation system that produces slides with a standardized, thin layer of stained cervical cells. In addition, the *i*<sup>3</sup> series includes FocalPoint which utilizes proprietary technology to distinguish between either normal thin-layer or normal conventional Pap smears and those that have the highest likelihood of abnormality.

#### *The PrepStain System (formerly AutoCyte PREP)*

Our PrepStain system consists of proprietary reagents, plastic disposables and automated equipment for preparing a thin-layer of cervical cells on a SurePath microscope slide. The SurePath slide preparation process begins with the clinician collecting a patient's cervical sample using a conventional collection device provided in the SurePath collection kit, in this case a cervical broom with a detachable head. The clinician then

immediately places and detaches the head of the collection device in a vial containing our proprietary SurePath preservative fluid, thereby retaining all of the cells from the collection device. The sample is thoroughly mixed, resulting in a randomized cell suspension which is removed from the vial and layered onto a proprietary liquid density reagent in a plastic centrifuge tube using our patented syringe device. Batch centrifugation is then conducted on the cell suspension to remove excess blood, inflammatory cells and other debris from the sample.

Once centrifugation is completed, the lab technician places the tube containing the separated diagnostic cells onto an automated pipetting system. This pipetting system then distributes the cervical cells in a thin-layer on the microscope slide and discretely stains the slide for subsequent analysis. A SurePath slide typically contains approximately 50,000 to 160,000 diagnostic cells that are distributed uniformly over a 13-mm diameter circle. PrepStain is currently capable of preparing and discretely staining approximately 48 thin-layer SurePath slides in approximately one hour.

We have also developed an automated accessory to the PrepStain system called PrepMate that reduces the number of manual preparation steps required on the PrepStain system. PrepMate is intended to reduce the time required to prepare samples for processing on the PrepStain instrument. The FDA approved PrepMate for use in the U.S. in May 2001.

#### *Advantages of PrepStain Over the Conventional Pap Smear Process*

We believe that the PrepStain system offers the following advantages over the conventional Pap smear process:

- *More Complete Sample Collection.* Because the clinician places the collection device directly into the SurePath vial, the entire patient sample is contained in our proprietary preservative fluid. Since all collected cells are retained, the sub-sample on the thin-layer preparation is more representative of the patient's specimen. In a conventional Pap smear process, as much as 80% of the cervical sample can be inadvertently discarded on the collection device after smearing the sample onto the slide.
- *Improved Sample Quality.* By eliminating variations in preparation techniques and the fixative spraying step from the sample collection process, PrepStain virtually eliminates air-drying, generates a more complete fixation, and provides a more standardized preparation process in a controlled, laboratory environment. This more uniform cell sample distribution also reduces cell clumping and obscuring from debris. We believe that SurePath thin-layer slides provide cytotechnologists with samples that are clearer, more representative and easier to diagnose than conventional Pap smear slides.
- *Improved Cytotechnologist Productivity.* In our clinical studies, some laboratories using PrepStain experienced a greater than 50% increase in cytotechnologist screening productivity. The impact on cytotechnologist efficiency is important to clinical laboratories because of the growing shortage of qualified cytotechnologists in recent years and the need to create and maintain a desirable working environment for cytology professionals.
- *Automated and Discrete Staining Function.* PrepStain includes a discrete, or individual, slide staining function performed by a computer-controlled robotic pipetting station. Unlike conventional Pap smear slides that are often manually stained in a batch process using common reservoirs of staining reagents, PrepStain's staining reagents are directly applied to individual slides. As a result, staining reagents are not shared among slides. We believe this reduces the risk of cross-contamination among cell samples that can lead to inaccurate diagnoses.
- *Multiple Testing Capability.* Because our proprietary SurePath preservative system enables the patient sample to be preserved for several months, it permits, if necessary, preparation of several slides from a single sample. We believe that the ability to perform adjunctive slide-based tests using a single sample, together with the improved quality of the slide itself, will reduce re-testing expenses typically associated with inconclusive Pap smear tests. The residual patient sample may also be used for other diagnostic protocols such as HPV testing, infectious disease testing and application of specific tumor

markers. Residual sample testing is under FDA review and will require FDA approval if and when such testing is determined to be viable.

#### *Advantages of PrepStain Over Other Thin-Layer Sample Preparation Systems*

We believe that PrepStain offers the following advantages over other thin-layer devices:

- *Improved Sample Quality.* The SurePath sample is processed through the PrepStain series of proprietary liquid-based reagents and centrifuge separation techniques designed to “enrich” the sample with a high concentration of diagnostic cells. The only other currently FDA-approved thin-layer device relies on membrane filtration. We believe that our cell enrichment process more effectively controls the incidence of infectious agents, mucus, inflammatory cells and other debris that may reduce the performance of membrane filtration systems. We believe that, in populations with high rates of gynecological infection, PrepStain’s cell enrichment process will result in a more representative slide sample that should ultimately lead to a reduction in uncertain or incorrect diagnoses.
- *Higher Throughput.* PrepStain has the capacity to produce approximately 48 thin-layer slide preparations in approximately one hour, using a hands-off robotic system. We believe the throughput capability of PrepStain to be the highest of any thin-layer product on the market today.
- *Improved Screening.* The cell circle on a SurePath slide is smaller than the cell circle on other available thin-layer devices, yet the number of diagnostic cells is approximately equal. We believe that the smaller cell circle, coupled with a lower incidence of infectious agents, mucus, inflammatory cells and other debris, should result in faster, more efficient screening by cytology professionals.
- *Familiarity with Sample Preparation Approach.* The PrepStain centrifugation and robotic liquid handling techniques are similar to conventional procedures already in use in clinical laboratories.
- *Discrete Staining Function.* Unlike other thin-layer devices that rely on batch staining using common reservoirs of staining reagents, PrepStain staining reagents are applied directly to individual slides. Discrete staining offers several benefits, including reduced risk of cross-contamination among cell samples, less degradation of the staining solution and less staining time and lower costs.
- *Increased Screening Output.* Unlike other thin-layer devices, slides prepared using the PrepStain instrument are approved by the FDA to be screened by our FocalPoint Slide Profiler instrument. Using this technology, up to 25% of slides screened by the FocalPoint can be archived without requiring further human review, resulting in time and labor savings to the laboratory. Further, use of the FocalPoint can accelerate the laboratory’s turnaround time on test results.

#### *FocalPoint Slide Profiler (formerly AutoPap Primary Screening System)*

FocalPoint Slide Profiler is a primary interpretation system designed to distinguish between normal and abnormal Pap smears. FocalPoint was approved by the FDA in May 1998 as a primary screening device for conventional Pap smear slides. In October 2001, the FDA approved the use of FocalPoint as a primary screening device for our PrepStain-prepared, SurePath thin-layer slides. FocalPoint uses visual intelligence algorithms to improve accuracy in the primary screening of conventional Pap smear slides and our SurePath thin-layer slides. As approved by the FDA, FocalPoint identifies up to 25% of slides as “within normal limits” and requiring no further review (sometimes referred to as “sort rate” or “no further review rate”). Cytotechnologists then manually screen the remaining slides with the assistance of FocalPoint’s ranked review report. This ranked review report shows the relative scores of the processed slides. At least 15% of the highest-ranking slides that are classified normal by manual review then undergo quality control re-screening. Outside the United States, the FocalPoint is used, in some instances, to identify up to 50% of slides “within normal limits.”

FocalPoint works with a range of staining procedures used on conventionally-prepared Pap smear slides. FocalPoint analyzes a Pap smear in about the same time as a cytotechnologist. It holds 288 Pap smear slides at once, is easy to load and unload and can operate continuously with minimal intervention for up to 24 hours

per day. We provide each clinical laboratory with on-site training, system documentation, a comprehensive quality assurance program and ongoing customer and technical support.

#### *Advantages of FocalPoint Slide Profiler Over Conventional Pap Smear Screening*

We believe the FocalPoint offers the following advantages over manual screening of Pap smears:

- *Improved Screening.* Clinical laboratories rely on the manual screening of Pap smear slides by cytotechnologists. The FocalPoint is the only instrument approved by the FDA to process Pap smears without human review. Clinical studies have shown that the use of FocalPoint to review conventionally prepared Pap smear slides results in the identification of significantly more abnormal slides as compared to the manual screening process. We believe that the FocalPoint-assisted laboratory is better able to correctly identify abnormal slides as compared to laboratories that rely only on manual Pap smear screening. We believe that laboratories using of FocalPoint will substantially improve their quality of practice, and have the potential to reduce their exposure to liability resulting from false-negative results.
- *Detection of Pre-Cancerous Cells.* In recent years the medical community has increasingly focused on improving the quality of women's healthcare. We believe that FocalPoint will allow laboratories to better detect pre-cancerous cervical conditions and cervical cancer, thereby improving the standard of care for female patients. Earlier detection and treatment of cervical cancer can lower risks of morbidity and death.
- *Increased Screening Output.* Currently, in the U.S. market there exists a shortage of trained and qualified cytotechnologists to review slides. By archiving up to 25% of slides requiring "no further review", the FocalPoint can reduce the number of Pap smears requiring cytotechnologist review and therefore increase a laboratory's overall screening capacity. The commercial laboratory industry is highly competitive, and improved turnaround on result reporting can be an important source of differentiation. By incorporating the FocalPoint, we believe laboratories have an opportunity to substantially improve their turnaround times for reporting results by eliminating and preventing backlogs from occurring due to existing labor shortages.
- *Improved Economics.* In the past several years, the U.S. market has transitioned from 100% conventional Pap smears to approximately in excess of 50% thin-layer prepared Pap smears. While we anticipate the trend toward thin-layer testing to continue, most laboratories currently offer a mix of both testing methods. For conventional Pap smears screened by the FocalPoint system, the national reimbursement limit amount is \$15.73 for each sample that falls within the category of slides classified as "within normal limits" and requiring no further review, or up to 25% of all slides screened. The national reimbursement limit for the remaining 75% or more of the slides screened using the FocalPoint system and requiring further review is \$21.00. This compares favorably to a \$14.00 national reimbursement limit for manual screening of conventional Pap smears. We believe that the FocalPoint offers laboratories an effective platform to transition to thin-layer testing while realizing the clinical and economic benefits of computerized screening of both SurePath slides and conventional Pap smears.

#### *FocalPoint GS*

In the fourth quarter of 2000, we launched the FocalPoint GS, the next generation of the FocalPoint system for use outside the United States. The FocalPoint GS further improves the screening process by automating the microscopic analysis of SurePath thin-layer slides or conventional Pap smears designated for further review by the FocalPoint Slide Profiler. The FocalPoint GS integrates our SlideWizard technology into the FocalPoint screening process. The FocalPoint instrument is interfaced to our SlideWizard platform and networked to one or more commercially available microscopes that have been equipped with computer-controlled automated stages for fast relocation of "fields of interest" on microscopic slides. During the initial screening process, and for each slide screened, the FocalPoint GS identifies and stores a pre-set number of "fields of interest" in which it has calculated a higher probability of abnormality. As with the FocalPoint Slide Profiler screening process, the FocalPoint GS identifies up to 25% of slides as "within normal limits" for which

no further review is required. For each of the remaining slides, the FocalPoint communicates the location coordinates of the "fields of interest" to the computer controlled microscope stage via the SlideWizard platform. The "fields of interest" are electronically highlighted for easy identification. This facilitates an abbreviated microscopic review and allows the cytotechnologist to quickly analyze the slide for the presence of cellular abnormality. Abnormal findings thus identified can be confirmed by full microscopic review. If no abnormality is identified during this rapid cytologic assessment, no further review is required.

We believe the established quality of the FocalPoint algorithms, coupled with the highly focused nature of location-guided screening, allow a laboratory to improve quality, increase capacity by up to 200% and alleviate backlogs and/or labor shortages.

We anticipate initiating clinical trials in the second half of 2002 to obtain data to support an application for U.S. approval of the FocalPoint GS by the FDA. Upon completion of these studies, we plan to submit a PMA supplement to the FDA for domestic approval of FocalPoint GS.

### **SlideWizard Product Line**

Our long-term product strategy involves the entry into the broader clinical laboratory automation market. Our SlideWizard product line consists of PC-based applications focused on the quantification of the nuclear DNA content of cells and of specific molecules in cells or tissue sections (immunohistochemistry and immunocytochemistry assays), the management and archiving of images and patient information, the exchange of data via telepathology and the creation of comprehensive reports combining color images and patient data. Our SlideWizard line of products include:

- A telepathology system for the transmission and interpretation of tissue specimens via remote telecommunication;
- A software-based image management, archiving and retrieval system for microscopic images;
- A system that performs quantitative analysis of DNA by quantifying Feulgen Stain, nuclear texture and morphology;
- A general purpose image analysis system for the recognition and quantification of virtually any stain application on a variety of biologic materials;
- ImageTiter, a method for automating measurement of antinuclear antibodies, as well as research applications in histopathology; and
- LGS, an electronic dotting and labeling system.

In November 1995, we received 510K clearance by the FDA to market the ImageTiter for automating antinuclear antibody testing. Our DNA and immuno-quantification applications are presently offered "For Research Only" in the United States. A SlideWizard workstation is also a component of the FocalPoint GS system which is currently sold only outside the United States. We expect to develop additional applications or modules in the field of tissue diagnosis and prognosis to run on the proprietary SlideWizard platform. We may elect to pursue regulatory clearance to market in the United States for additional SlideWizard applications currently under development or developed by us in the future.

### **Molecular Diagnostics Products**

We are developing oncology products and services under our collaboration with BD. These products and services will be based upon genomic and proteomic markers identified through discovery research, conducted at Millennium under its existing research and development agreement with BD. TriPath Oncology will clinically validate and develop these proprietary cancer markers into commercial diagnostic and pharmacogenomic oncology products and services. Commercial responsibilities for resulting products will be shared between BD and TriPath Oncology. BD will continue to fund additional discovery research activities at Millennium.

We believe that our automated visual intelligence technology can be used for other diagnostic tests that involve microscopic analysis of biological specimens on glass slides, such as sputum, blood, urine or other samples. To develop our technologies for other applications, we will need to adapt software algorithms to analyze each of these other samples.

In February 2002, we executed a letter of intent to collaborate with AmeriPath, Inc., a leading national provider of cancer diagnostics, genomic, and related information, on the validation and clinical use of a novel gene expression assay for malignant melanoma. According to the terms of the letter of intent, AmeriPath will validate reagents and procedures to incorporate a novel gene target for malignant melanoma. The assay results will be analyzed using our Extended SlideWizard imaging and telepathology platform. We expect to finalize this arrangement in May 2002, subject to obtaining various authorizations and approvals, as well as the negotiation and execution of a definitive agreement.

Commercial development of additional products and services resulting from our collaboration with BD is expected to begin in 2004 for the staging and prognosis of cervical, breast and prostate cancer followed by assays for the early detection and monitoring of ovarian, breast, prostate and colon cancer in 2005. In the interim, TriPath Oncology is investigating a number of potential strategic alliances to complement, accelerate and augment the activities arising from the collaboration with BD.

### **Marketing and Sales**

Automation of the historically labor intensive *in vitro* diagnostic industry has provided one of the largest opportunities for cost reduction in health care services, a necessity driven by the current health care environment. Today, virtually all sectors of the clinical diagnostics industry have been automated to a significant extent. Automating strategies that have employed digital technology and robotics, and specific techniques for sensing and identifying specific analytes, such as radioimmunoassay, enzyme and enzyme-linked immunoassay, flow cytometry, immunohistochemistry, and emerging DNA based techniques, such as polymerase chain reaction and *in situ* hybridization, have redefined the practice of clinical laboratory medicine. Laboratory application of automated diagnostic systems has resulted in reduced labor costs, more reliable diagnosis in shorter periods of time and the availability of digitally formatted information which facilitates the independent evaluation of cost-effectiveness and the determination of evidence based core pathways designed to optimize patient care. Concomitantly, the steadily increasing trend toward complete process automation has driven the bottom line growth of suppliers of diagnostic reagents and automating medical devices.

The two exceptions to this pattern of rapidly increasing automation in *in vitro* diagnostics have been the cytopathology and histopathology laboratories, where the standard of practice is defined by the visual examination and analysis of cells and tissues. Cancer, in one of its many forms, is the disease most often considered and evaluated in laboratories. Samples being examined are typically tissue biopsies or Pap smears. The collection and preparation of these samples have been resistant to the general wave of automation because they have required human observation and analysis under a microscope. The observer is required to identify and interpret what are often very subtle changes within human tissues. These are often very complex, time consuming, tedious and exacting tasks. The practices of cytopathology and histopathology remain largely manual and labor intensive.

Previously, the complex biologic structural, or morphologic, changes exhibited by cancer were considered too subtle for identification and interpretation by computer or other automated apparatus. The conventional wisdom was that cell and tissue diagnosis is an intrinsically qualitative process that requires subjective visual judgment. However, as the science of image processing and analysis has matured, it has become increasingly accepted that these "subjective" signals can be redefined in terms of mathematical algorithms. These algorithms, in turn, provide the basis for computerization and an automated solution.

As the last frontier for automation in *in vitro* diagnostics, the cytopathology and histopathology laboratories present a major opportunity. We believe that automation of these laboratories through computerized image analysis will:

- significantly reduce labor costs;
- drive improved standardization, reproducibility, and quality control;
- enhance the efficiency of treatment by increasing the accuracy and precision of diagnosis, and;
- provide an opportunity to collect digitalized information to facilitate the development of highly specific and targeted outcome patient care programs.

Automated slide preparation and screening products were introduced into the cervical cancer screening market in the mid-1990's. We expect to benefit from the increased awareness and growing acceptance of these new technologies.

### *Marketing Strategy*

We currently market our cervical cytology products as part of an integrated system and have been combined them under our "i<sup>3</sup>" series product line. Our SurePath, PrepStain and FocalPoint systems, together, provide the only integrated solution for sample preparation, processing, staining and computerized analysis of liquid based thin-layer preparations. We began limited international commercial sales of our PrepStain system in 1993, and commenced commercialization in the United States following FDA approval in 1999. We began placements of AutoPap QC systems, a predecessor to the current FocalPoint system, in 1995 and of FocalPoint system in 1998. FocalPoint is the only fully automated Pap smear screening device to receive regulatory clearance for marketing in the United States.

The principal market for gynecological applications of PrepStain and FocalPoint are clinical laboratories worldwide. Clinical laboratories are also the primary focus for patients, physicians and third party payers in connection with the Pap smear process. In an effort to facilitate the adoption of our products, we have engaged the necessary sales professionals to educate and promote our products to each of these groups. Furthermore, we have contractual partnerships with organizations associated with physician education and third party payer/reimbursement support. We view these partnerships as a necessary extension of our business given their potential to fuel our growth and expansion into new technologies.

The principal market for non-gynecological applications of PrepStain is also clinical laboratories worldwide, although these applications are performed in significantly lower quantities than cervical cancer screening applications. Non-gynecological applications for the detection of cancer are performed on body fluids, including urine samples, respiratory specimens and a variety of fine-needle aspirates of specific organs.

We market our products to domestic and foreign clinical laboratories through direct sales activities in the United States and primarily through distributors in international markets. In the fourth quarter of 2000, we significantly expanded our marketing and sales activities to accelerate the commercialization of our products. We hired approximately 15 additional laboratory sales representatives to increase contact with laboratories. Through an alliance with Nelson Professional Sales ("NPS"), we engaged the physician market directly for the first time by adding approximately 25 physician-directed representatives on a contract basis, and augmented our direct sales efforts. In July 2001, we added 15 additional physician-directed representatives to our sales force through our agreement with NPS, resulting in a sales and marketing force of nearly 100 individuals. Our sales force includes individuals engaged directly with the OB-GYN and primary care physician market to sell the PrepStain system. Additionally, our expanded laboratory sales force has been organized under geographical segments to better address potential customers around the country.

We have also increased our marketing efforts by directing resources toward various marketing-related initiatives designed to promote brand identification and awareness, increase market acceptance of our products and services and enhance product management. To further educate and reinforce the benefits of our products, we initiated a long-term partnership with a third party physician/peer selling organization that will continue into 2002. An important element of our marketing strategy is to achieve broad market acceptance of our

integrated product consisting of our PrepStain thin-layer slides for cervical cancer screening by the FocalPoint system. In implementing this strategy, we will seek to address the needs of the constituencies described below.

*Clinician/OB-GYN.* The clinician requires a simple collection technique that results in an accurate and adequate sample from the patient. We believe that PrepStain's patented cell enrichment process and SurePath's single collection device facilitate high quality results using a simple collection technique.

*Large clinical laboratories.* Conventional Pap smear testing has become a concentrated market in the United States. We believe that approximately 50% of cervical cancer test volume is concentrated among a relatively small number of large laboratories. We believe the following factors will enable us to market PrepStain and FocalPoint successfully to this concentrated market segment:

- PrepStain's high throughput and cost-effectiveness;
- FocalPoint's ability to identify more abnormal slides than conventional methods;
- FocalPoint's ability to show improved specificity over current practice; and
- FocalPoint's ability to screen both conventional and liquid-based slides.

Moreover, the pressures associated with rising health care costs, rising litigation costs, and the limited supply of qualified cytotechnologists should further facilitate adoption of PrepStain and FocalPoint by the large laboratory market.

*Medium and small clinical laboratories.* We also intend to continue to devote a portion of our marketing and sales resources to targeting medium-sized and small clinical laboratories. Hospital consolidation, particularly the consolidation of laboratories of larger hospitals, has created a medium-sized customer for our products. We expect that the medium-sized and small clinical laboratory segment of the market generally will utilize our IPO or equipment rental programs.

*Third-party payers.* We have gained a significant level of market acceptance of our products by third party payers by devoting additional resources in the area of reimbursement. We plan to continue promoting the clinical and economic benefits of our PrepStain and FocalPoint systems to nationally managed care providers, major private insurers and other third-party payers, including the benefits of their combined use. We have demonstrated that the overall cost savings to the health care system, resulting from the early detection of cervical cancer and the decrease in unnecessary repeat Pap smears, biopsies and colposcopies resulting from improved specimen adequacy, more than offset the cost of our products. See also "Third-Party Reimbursement" below.

### *Sales Strategy*

We generate PrepStain related revenue from either the sale, rental or lease of PrepStain systems and from the sale of the related SurePath test kits, comprised of proprietary reagents and other disposables. Additionally, we generate revenue from service contracts on the PrepStain systems. For system sales, customers purchase the PrepStain instrument and make separate purchases of test kits. Revenue recognition on the sales of the PrepStain system occurs at the time the instrument is installed and accepted at the customer site. For system rentals, PrepStain systems are placed at the customer's site free of charge and the customer is obligated to purchase SurePath test kits for a fixed term, typically three or four years. Under these rental arrangements, there is no revenue recognized on the PrepStain system hardware. For system leases, we offer two alternatives. The first alternative involves a lease arrangement directly through us for the PrepStain instrument and related hardware. These leases require monthly payments for the equipment and are typically for 36 or 48-month terms. The customer purchases the PrepStain reagents and disposables that run on the instruments separately from the lease on an as-needed basis. Under these lease arrangements, there is no revenue recognized on the PrepStain system hardware. The second alternative is known as our Integrated Purchase Option, or "IPO" program, under which PrepStain systems are purchased by a third party financial institution and are placed at the customer's site free of charge. The customer then purchases the PrepStain reagents at a price that is sufficient to repay the financial institution for the cost of the PrepStain instrument and to provide us with an acceptable profit on the reagents and disposables. Under the IPO program, we

record revenue for the instrument sale at the time the instrument is installed and accepted at the customer site. During 2001, our strategy was to emphasize system leases versus the IPO program for the instruments placed with customers and thereby retaining a greater percentage of our ongoing, higher margin PrepStain reagent revenue stream. However, regardless of whether PrepStain systems are sold, rented or leased, each system placed typically provides a recurring revenue stream as customers process our SurePath test kits.

We generate FocalPoint related revenue from the direct sale of FocalPoint systems, and from the placement of FocalPoint systems under fee-per-use contracts. In the latter case, fee-per-use revenue commences in the month a system is initially placed in commercial use at a customer site and consists of per-slide monthly billings, fixed rental billings, or certain fee-per-use contracts that require minimum payments. Domestic customers may also elect to purchase the FocalPoint instrument under the IPO program. We have recently converted fee-per-use contracts to direct sale arrangements. Additionally, we generate revenue from service contracts on FocalPoint systems.

We also generate revenue from either the sale or rental of our SlideWizard line of products and from service contracts on these products. For system sales, customers purchase the products through distributors in countries where such relationships exist. Where distributor arrangements do not exist, we sell these products directly to the customer.

#### *Marketing and Sales Organization*

We currently utilize in excess of 110 full-time marketing and sales personnel worldwide, including approximately 40 people through our arrangement with NPS, to market, sell and provide after-sale support of our products. Our agreement with NPS is scheduled to end in mid-2002, unless extended. We are presently exploring various options in anticipation of the expiration of the agreement, including continuing with a contracted physician sales force and offering employment to individuals contracted to us under the agreement, subject to its terms and conditions regarding offers of employment. We expect to selectively increase our worldwide base of sales and marketing employees, if and where opportunities arise, by the end of 2002.

In the United States, we have expanded our efforts to market our cervical cancer screening products through a direct sales force. This direct sales organization is focused both on the physician market, primarily OB-GYN and primary care physicians, and the laboratory market to achieve market penetration and availability of our products. Further, our marketing organization is expanding our presence in the marketplace through increased advertising and promotion, company-sponsored seminars and trade shows, and peer selling activities. We also plan to continue to increase the number of our reimbursement specialists with an emphasis on managed care organizations and other third-party payers to achieve maximum reimbursement levels and to further stimulate demand for our products. We will also seek co-marketing agreements with sales organizations of major reference laboratories to market our products directly to health care providers.

In international markets, we market and sell our products primarily through a distribution network. To support these efforts, we employ seven full-time personnel, consisting of sales professionals, product managers and after-sales support personnel located in Europe. We anticipate that these distributor organizations will ultimately assume responsibility for all sales and after sales support activities, as well as a portion of our marketing activities. We have employed both large distribution organizations with products focused on the clinical diagnostic market, and smaller distribution organizations with products focused specifically on the anatomic pathology market to distribute our products worldwide.

We offer after-sale support services, including customer training, product installation, telephone technical support and repair service directly to customers in the United States. Our support personnel are located both at our headquarters and in select major metropolitan areas. Internationally, we provide these services through our employees and distributor organizations.

## **Manufacturing**

### *FocalPoint*

We currently assemble, integrate and test the electronic, mechanical and optical components and modules of FocalPoint, and PrepMate, the front-end accessory to the PrepStain, at our Redmond, Washington facility. Our operations have produced sufficient FocalPoint systems to meet customer demand since we began commercial operations in 1996 and we believe we have sufficient capacity to meet anticipated near-term customer needs for our FocalPoint and PrepMate products.

We purchase all components for the FocalPoint system from outside vendors. Several components of the FocalPoint are supplied by sole-source vendors. If any of these sole-source suppliers are unable to provide an adequate and constant supply of components, we will need to modify any components provided by additional or replacement suppliers. We may be unable to quickly establish additional or replacement sources of supply for several FocalPoint components. In addition, we may need to obtain regulatory approval to substitute certain components. If one of our vendors becomes unable to supply acceptable components in a timely manner and in the quantity required, we may need to delay or halt our manufacturing process.

### *PrepStain*

We currently assemble, test and package components of PrepStain at our manufacturing facility in Burlington, North Carolina. We also manufacture our SurePath preservative fluid and our PrepStain line of reagents and stains for PrepStain at the Burlington facility. We believe that our existing manufacturing and assembly processes are adequate to meet the near-term, full-scale production requirements of our SurePath and PrepStain systems for cervical cancer screening.

We purchase certain PrepStain instrument components from a single supplier in Europe. The consumable items used with PrepStain are purchased from a variety of third-party vendors, some of which are sole-source suppliers. We have a multi-year, exclusive contract with the supplier of manufactured instrument components that are incorporated into our PrepStain product line, which expires in December 2004. Pricing for components is fixed, but is subject to adjustment based upon changes in raw material costs. Our obligation to use this supplier exclusively for the components is contingent upon this supplier supplying us at prices competitive with those offered by third parties on similar terms, and upon this supplier meeting our quality and production requirements. We believe that the supplier has sufficient capacity to meet our present and future requirements for these components.

### *SlideWizard Products*

We currently manufacture the majority of our SlideWizard product line at our Burlington, North Carolina facility. We also manufacture a limited number of our SlideWizard instruments and integrate them into the FocalPoint GS at our Redmond, Washington facility. We believe we have sufficient capacity to meet anticipated near-term customer demand for our SlideWizard product line.

Our SlideWizard products consist primarily of off-the-shelf components and proprietary software. The components are supplied by a variety of vendors, some of which are sole-source suppliers. We have been integrating and selling extended SlideWizard products since 1993.

### *Molecular Diagnostics*

We anticipate that reagents for melanoma gene targets will be manufactured by BD. We believe BD has adequate capacity and production capability to satisfy customer demand and technical product requirements. We will consider in-house or third-party manufacturing of molecular diagnostic products that we develop.

### *Our Suppliers*

Several components of our products are supplied by sole-source vendors. Subject to any of our exclusive contractual arrangements, we may seek to establish relationships with additional suppliers or vendors for

components of our products. If any of our current or future sole-source suppliers are unable to provide an adequate and constant supply of components, we will need to modify any components provided by additional or replacement suppliers for use in our products. We may be unable to quickly establish additional or replacement sources of supply for several of these components. The incorporation of new components, or replacement components from alternative suppliers into our products may require us to submit PMA supplements to, and obtain further regulatory approvals from, the FDA before marketing the products with the new or replacement components. There can be no assurance that we will be able to obtain the necessary approvals. If one of our vendors becomes unable to supply acceptable components in a timely manner and in the quantity required, we may need to delay or halt our manufacturing process. Any delay or cessation of manufacturing could adversely affect our business.

### *Manufacturing Standards*

Our manufacturing process is subject to extensive regulation by the FDA, including the FDA's Quality System Regulation ("QSR," also known as Good Manufacturing Practice, or "GMP") requirements. As part of the FDA regulatory process, we face periodic FDA inspections and other periodic inspections by U.S. and foreign regulatory agencies. See "Governmental Regulation." Both the Burlington, North Carolina and Redmond, Washington facilities are subject to periodic FDA inspections. Failure to comply with the FDA's QSR requirements in the future would materially impair our ability to achieve or maintain commercial-scale production. In addition, if we are unable to maintain full-scale production capability, acceptance by the market of PrepStain, SurePath and FocalPoint would be impaired, which in turn would have a material adverse effect on our business.

In addition to QSR requirements, we are required to meet requirements relating to ISO 9001 certification, including European regulatory requirements. A European "CE" certification is required to successfully sell PrepStain and FocalPoint in Europe according to certain directives of the European Union. The addition of other European directives may require us to further demonstrate compliance with new or modified requirements in order to apply the CE mark specific to those directives. The OEM supplier of the PrepStain instrument components has ISO 9001 certification and has obtained CE certification for the main PrepStain component. We obtained CE compliance for the entire PrepStain system. The FocalPoint System is certified to EN55022:94/CISPR 22, Class A, EN 50082-1 92, AS/NZS2064/CISPR 11, Class A.

We obtained ISO 9001 certification at our Burlington, North Carolina facility in 1999. Compliance audits were conducted on our Burlington, North Carolina facility by a certified ISO auditor in May 2000, January 2001, June 2001, and January 2002. We were subsequently notified in each case that the facility had no outstanding deficiencies and had successfully passed each of the audits.

We have initiated efforts to obtain ISO 9001 certification at our Redmond, Washington facility.

### **Research and Development**

Our research and development programs are currently focused on four major goals:

- development of molecular diagnostic and pharmacogenomic tests for malignant melanoma and cancer of the cervix, breast, ovary, colon and prostate through our collaboration with BD.
- continued improvement and streamlining of the FocalPoint system and FocalPoint GS product;
- additional enhancement of the PrepStain system, including adjunctive testing using the SurePath preservative solution, improvement of related PrepStain reagents and disposables, and further streamlining and automating the PrepStain slide processor with regard to the preparation and handling process; and
- development of additional SlideWizard applications with scalable automation capabilities to address the needs of the broader pathology automation market, as well as the needs of potential strategic partners.

TriPath Oncology is developing molecular diagnostic and pharmacogenomic tests for malignant melanoma and cancer of the cervix, breast, ovary, colon and prostate through our collaboration with BD. The goal of this research and development program is to develop tests designed to identify cancer at its earliest stage and provide individualized diagnostic and prognostic information for patients with cancer. We are also seeking alternative applications for our technologies through internal research and development, as well as through strategic partnerships with other companies.

We completed the relocation of BD's molecular oncology program to temporary facilities in North Carolina at the end of December 2001. In January 2002, we signed a multi-year lease on approximately 22,000 square feet of laboratory and office space to principally house the TriPath Oncology operations. This space will be ready for occupancy by mid-2002. TriPath Oncology has assumed complete responsibility for both assay and instrument development-related activities. We anticipate establishing an in-house laboratory to facilitate the validation and commercialization of assays developed from these activities.

Enhancements to both FocalPoint and PrepStain are specifically designed to increase the instruments' efficiency, ease of use, reliability and cost-effectiveness. This also includes initiatives directed at extending the shelf life of the SurePath and PrepStain lines of reagents and preservatives used with the PrepStain system. We also plan to explore alternative uses for adjunctive testing using our SurePath preservative fluid and to seek approval for the use of alternative collection devices in connection with the specimen collection process related to the PrepStain system.

We are continually enhancing our SlideWizard line of products. We have expanded this product line to a modular concept which allows rapid prototyping and product development. The degree of automation for the resulting applications can be adjusted to the needs of the corresponding market, from interaction to complete automation. This technology takes advantage of our intellectual property portfolio and will be primarily applied to complement the existing portfolio of applications with new developments focused on gene or protein based cancer staging and prognostic testing.

There can be no assurance that any product enhancement or development project that we undertake, either currently or in the future, will be successfully completed, receive regulatory approvals or be successfully commercialized. The failure of any such enhancement or project to be completed, approved or commercialized could prevent us from successfully competing in our targeted markets and could have a material adverse effect on our business.

As of December 31, 2001, we had approximately 65 employees engaged in research and development activities. Our expenditures for research and development were approximately \$11.2 million, \$8.6 million, and \$6.7 million for the years ended December 31, 1999, 2000 and 2001, respectively.

### **Third-Party Reimbursement**

Most private third-party medical insurance providers and governmental agencies offer reimbursement for laboratory testing associated with routine medical examinations, including Pap smears. In the United States, the level of reimbursement by those third-party payers for Pap smears varies considerably. On average, there has been a general increase in reimbursement amounts due to recent minimums established by the Center for Medicare and Medicaid Services ("CMS") which administers Medicare, (formerly known as Health Care Financing Administration, or HCFA). Third-party healthcare payers in the United States are increasingly sensitive to containing healthcare costs and heavily scrutinize new technology. Third-party payers may also influence the pricing or perceived attractiveness of our products and services by regulating the maximum amount of reimbursement they provide. Successful commercialization of PrepStain and FocalPoint for cervical cancer screening in the United States and some other countries will depend on the availability of reimbursement from such third-party payers. Because the up-front costs of using our products are typically greater than the cost of the conventional Pap smear, we have worked to convince third-party payers that the overall cost savings to the health care system, resulting from early detection of cervical cancer and its precursors will more than offset the cost of our products.

We have focused on obtaining coverage and reimbursement from major national and regional managed care organizations and insurance carriers throughout the United States. In early 1998, we established a reimbursement team to work with third-party insurers and managed care organizations to establish and improve third-party reimbursement rates for our products. Most third-party payer organizations independently evaluate new diagnostic procedures by reviewing the published literature and the Medicare coverage and reimbursement policies on the specific diagnostic procedures. To assist third-party payers in their respective evaluations of PrepStain and FocalPoint, we provide scientific and clinical data to support our claims of the safety and efficacy of our products. We focus on improved disease detection and long-term cost savings benefits in obtaining reimbursement for PrepStain and FocalPoint for cervical cancer screening.

In a Program Memorandum to Regional Intermediaries/Carriers dated March 14, 2001, CMS announced it had established National Limitation Amounts for the CPT reimbursement codes that relate to our products. CMS set the national reimbursement limit at \$28.00 for the manual screening (CPT code 88142) and re-screening (CPT code 88143) of each liquid-based, thin-layer prepared using the PrepStain system.

For conventional Pap smears screened by the FocalPoint system, the national limit amount is \$15.73 for each sample which falls within the category of slides classified as "within normal limits" and requiring no further review, or up to 25% of all slides screened (CPT code 88147). The national limit for the remaining 75% or more of the slides screened using the FocalPoint system and requiring further review (CPT code 88148) is \$21.00. We do not believe these limits will adversely impact our current pricing strategy or reduce the demand for our products.

In connection with the FDA's approval of the use of FocalPoint to screen PrepStain slides, we submitted information to the AMA CPT Editorial Committee necessary for the establishment of new CPT codes that reflect this new procedure. We anticipate the assignment of new CPT codes available for use with the January 2003 codebook revision. Until such time as codes are assigned, laboratories using our integrated system will be advised to report utilizing the miscellaneous cytopathology code (CPT code 88199). In the interim, our reimbursement team will continue working with our laboratory customers, and their third-party payers, to introduce the new procedure, define reporting requirements, and assist in the establishment of reimbursement rates. In consideration of the overall acceptance of both the PrepStain and the FocalPoint by third party medical insurance payers and governmental agencies, individually, we anticipate that the integration of these devices will receive similar overall acceptance with respect to coverage and reimbursement.

Reimbursement for laboratory testing is generally based upon the level of technical complexity required to perform the test. Because most tumor marker immunoassays and immunohistochemical procedures are highly automated on instrumented platforms, reimbursement levels are typically significantly lower than for more extensive procedures associated with DNA analysis, nucleic acid amplification and in situ hybridization techniques. Through the development of molecular oncology products and services, We will determine the most appropriate test configuration and format based on clinical performance, manufacturability, laboratory ease-of-use, anticipated throughput requirements and reimbursement considerations.

### **Proprietary Technology and Intellectual Property**

We currently hold over 110 issued or allowed United States patents and have six United States patent applications pending. We also hold over 100 foreign patents and have applied for patent protection for certain aspects of our technology in various foreign countries. We acquired many of these patents in the merger of AutoCyte and NeoPath and the acquisition of the intellectual property and technology of Neuromedical Systems, Inc. We further expanded our patent portfolio through the acquisition of the intellectual property of Cell Analysis Systems from BD in September 1999. Our patents cover system components, such as the disaggregation syringe, the PrepStain process, and various aspects of our high-speed image-interpretation technology, as applied to cytopathology and histopathology. Because of the substantial length of time and expense required to bring new products through development and regulatory approval to the marketplace, we rely on a combination of patents, trade secrets, copyrights and confidentiality agreements to protect our proprietary technology, rights and know-how. We intend to continue to pursue patent protection where it is available and cost-effective, both in the United States as well as in other countries. Most of our existing

United States and foreign patents will expire between 2012 through 2019. A few of our foreign patents will expire as early as 2003. There can be no assurance, however, that the claims allowed in any of our existing or future patents will provide competitive advantages for our products, or will not be successfully challenged or circumvented by our competitors.

Under current law, patent applications in the United States and in foreign countries are generally maintained in secrecy for a period after filing. The right to a patent in the United States is attributable to the first to invent, not the first to file a patent application. We cannot be sure that our products or technologies do not infringe patents that may be granted in the future pursuant to pending patent applications or that our products do not infringe any patents or proprietary rights of third parties. There can be no assurance that a court would rule that our products do not infringe other third-party patents or would invalidate such third-party patents. We may incur substantial legal fees in defending against a patent infringement claim or in asserting claims of invalidity against third parties. For example, in September 1999, Cytyc filed suit against us alleging that our CytoRich proprietary preservative fluid infringed Cytyc's patent titled "Cell Preservative Solution," and in May 2000, Cytyc filed another suit against us alleging that we had distributed misleading information to current and potential purchasers of Cytyc's products. In both cases, we denied all of Cytyc's claims and in January 2001, we settled all litigation with Cytyc. In the event that we are determined to be infringing any claims of third-party patents and such claims are upheld as valid and enforceable, we may be required to pay damages, prevented from selling our products, required to obtain a license from the owners of such patents or required to redesign our products to avoid infringement. There can be no assurance that such licenses would be available or, if available, would be on terms acceptable to us or that we would be successful in any attempt to redesign our products or processes to avoid infringement. Our failure to obtain these licenses or to redesign our products would have a material adverse effect on our business, financial condition and results of operations.

We have entered into confidentiality agreements with all of our employees who we believe should sign such agreements, and several of our consultants and third-party vendors. These agreements also require employees and consultants to disclose to us ideas, developments, discoveries or inventions they conceive during employment or consultation. They also must assign any proprietary rights in any inventions conceived or developed while employed by us if such relate to our business and technology. These agreements may not provide meaningful protection for our confidential information if there is unauthorized use or disclosure of our proprietary information. There can be no assurance that the obligations of our employees and consultants and third parties with whom we have entered into confidentiality agreements to maintain the confidentiality of trade secrets and proprietary information, will effectively prevent disclosure of our confidential information. There also can be no assurances that our trade secrets or proprietary information will not be independently developed by our competitors.

We have registered trademarks in the United States for AUTOCYTE®, AUTOCYTE QUIC®, AUTOPAP®, CYTORICH®, IMAGETITER®, NEOPATH®, PAPMAP®, PREPAP®, and SLIDEWIZARD®. We have pending U.S. registrations for I<sup>3</sup> SERIES™, FOCALPOINT™, PrepMate™, PREPSTAIN™, SUREPATH™, TRIPATH CARE TECHNOLOGIES™, and TRIPATH IMAGING™. Registered trademarks abroad are maintained in Argentina, Belgium, Brazil, Chile, China, Denmark, France, Germany, Greece, Hong Kong, Italy, The Netherlands, Portugal, Russia, Taiwan, and the United Kingdom for AUTOCYTE®, AUTOPAP®, and PAPNET®. We are currently pursuing registrations abroad for FOCALPOINT™, PrepMate™, PREPSTAIN™, SLIDEWIZARD®, SUREPATH™, TRIPATH CARE TECHNOLOGIES™, and TRIPATH IMAGING™. In addition to trademark activity, we issue a copyright notice on all of our documentation and operating software. There can be no assurance that any trademarks or copyrights that we own will provide competitive advantages for our products or will not be challenged or circumvented by our competitors. Litigation may be necessary to defend against claims of infringement, to enforce patents, trademarks and copyrights, or to protect trade secrets and could result in substantial cost to, and diversion of effort by, us. There can be no assurance that we would prevail in any such litigation. In addition, the laws of some foreign countries do not protect our proprietary rights to the same extent, as do the laws of the United States.

## Competition

The cervical cancer screening market is comprised of the conventional Pap smear process and certain technologies that have been introduced in recent years, or are currently under development to provide improvements over the conventional Pap smear process. Our competitors in the development and commercialization of alternative cervical cancer screening technologies include both publicly traded and privately held companies. Alternative technologies known to us have focused on improvements in slide sample preparation, the development of automated, computerized screening systems and adjunctive testing technologies. Nevertheless, some competitors' products have already received FDA approval and are being marketed in the United States. In addition, one of our competitors has greater financial, marketing, sales, distribution and technical resources than us, and more experience in research and development, clinical trials, regulatory matters, customer support, manufacturing and marketing.

We believe that our products will compete on the basis of a number of factors, including slide specimen adequacy, screening sensitivity, ease of use, efficiency, cost to customers and performance claims. We believe a fully automated solution incorporating collection, preparation, staining, and computerized imaging for liquid based thin-layer preparations is required for sustaining our competitive advantage. While we believe that our products will have competitive advantages based on some of these factors, there can be no assurance that our competitors' products will not have competitive advantages based on other factors, including earlier market entry, which may adversely effect market acceptance of PrepStain and FocalPoint. Moreover, there can be no assurance that we will be able to compete successfully against current or future competitors or that competition, including the development and commercialization of new products and technologies, will not have a material adverse effect on our business. Our products could be rendered obsolete or uneconomical by technological advances of our current or potential competitors, the introduction and market acceptance of competing products, or by other alternative approaches for cervical cancer screening.

Our primary competitor in thin-layer slide preparation is Cytoc Corporation. Cytoc's systems, the ThinPrep 2000 and ThinPrep 3000 Processors, are based on a membrane-filtration separation system rather than the centrifugation approach used in our PrepStain process. The Cytoc ThinPrep systems are presently the only other thin-layer sample preparation systems approved by the FDA as a replacement for the conventional Pap smear. They are also used for non-gynecological applications. The FDA has allowed Cytoc to conclude in the discussion section of the package insert for ThinPrep 2000 and ThinPrep 3000, that the sample preparation is "...significantly more effective than the conventional Pap smear for the detection of Low Grade Squamous Intraepithelial and more severe lesions in a variety of patient populations." The FDA has also allowed Cytoc to conclude in the package insert that specimen quality "...is significantly improved over that of conventional Pap smear preparation in a variety of patient populations."

In addition, in October 1996, Cytoc announced a non-exclusive co-marketing agreement with Digene Corporation. Digene has developed a product that detects the presence or absence of HPV in pre-cancerous cervical lesions. In September 1997, the FDA approved PMA supplements submitted by Cytoc and Digene enabling testing for HPV directly from Cytoc's ThinPrep process cell suspension. We are presently working with Digene on a PMA supplement for use of our SurePath cell suspension with Digene's HPV test in the United States. In Europe, the SurePath cell suspension is already in routine use with Digene's HPV test. In January 2000, Cytoc and Quest Diagnostics announced a multi-year agreement naming ThinPrep as the exclusive liquid-based cervical cancer screening methodology for Quest. In October 2000, Cytoc announced an exclusive U.S. strategic alliance for women's health with Roche Diagnostics. Further, in January 2001, Cytoc announced an exclusive co-promotion agreement with Digene Corporation surrounding the use of Digene's HPV test using the Cytoc preservative solution. Additionally, Cytoc announced its submission to the FDA of its application for approval for an automated screening device for use with slides prepared using its slide preparation systems.

In February 2002, Cytoc and Digene announced their intention to merge. The proposed transaction is subject to review by the Federal Trade Commission under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. The Federal Trade Commission has extended its investigation beyond the initial 30-day waiting period and has requested additional information from Cytoc pertaining to the proposed merger. Cytoc's

success with implementation of any of the foregoing arrangements or marketing initiatives may make it more difficult for us to promote PrepStain and FocalPoint in markets in which we compete with Cytoc. Additionally, the successful completion of the Cytoc-Digene merger could prevent us from incorporating HPV testing into our existing products which could have a material adverse effect on our business.

We also face several competitors, or potential competitors, in the imaging field. To date, the FocalPoint system is the only FDA-approved device for the automated primary screening of PrepStain, thin-layer, and conventional, Pap smear slides. Cytoc has announced its submission to the FDA its application for approval for an automated screening device for use with slides prepared using its slide preparation systems. Other competitors include ChromaVision Medical Systems, Inc., which develops, manufactures and markets an automated cellular imaging system to assist in the detection, diagnosis and treatment of cellular diseases such as cancer and infectious disease, and Applied Imaging Corporation, which develops and markets automated genetic testing systems and imaging systems used in cancer pathology and research which are capable of sending digital images electronically for remote review and consultation.

Competition in the field of cancer diagnostic products is concentrated in a few areas and is expected to further intensify. Aside from mammography screening for breast cancer, the *in vitro* cancer diagnostics market consists primarily of tumor marker immunoassays. The cancer immunoassay market encompasses a number of blood-based tumor marker tests that are utilized extensively to assess therapeutic response and monitor for disease recurrence but have limited applications for screening due to their lack of sensitivity and specificity. Currently, prostate specific antigen (PSA) is the only blood based tumor marker that is universally utilized for cancer screening. Among the companies competing in the tumor marker immunoassay market are Abbott Diagnostics, Bayer Diagnostics, Roche Diagnostics, Ortho Clinical Diagnostics, Beckman-Coulter and Dade-Behring.

We believe that genomic and proteomic-based assays will likely provide a more accurate, disease-specific understanding of cancer to improve the clinical management of cancer. Although there are a number of companies that are investing in genomic and proteomic discovery research, few have invested as broadly in the cancer diagnostics area as we have through our relationship with BD. We view our primary competitors in this area to be Abbott Diagnostics, Bayer Diagnostics, and Roche Diagnostics. Abbott Laboratories, through its acquisition of Vysis, Inc., develops and markets clinical laboratory products targeting DNA chromosomal and genomic abnormalities for cancer and pre- and post-natal genetic disorders. Bayer Diagnostics and Roche Diagnostics operate in the immunoassay and tumor marker markets.

In addition to immunoassay based tests, we believe the staging, prognosis and prediction of outcomes will also be heavily influenced by the assessment of special stains utilizing immunohistochemical (IHC) and *in situ* hybridization techniques on tissue specimens. The primary companies currently competing in this area are Dako Corporation and Ventana Medical Systems. Both companies specialize in automated IHC staining instrumentation and offer a wide range of validated IHC tumor markers.

We also have several competitors with competing technology in the molecular diagnostics field. TriPath Oncology faces a host of competition from companies like F. Hoffmann-La Roche, Abbott Laboratories and Bayer, all of which have announced active programs in this area. There can be no assurance that these or other competitors will not succeed in developing technologies and products that are more effective, easier to use or less expensive than those which we currently offer or are developing, or that would render our technology and products obsolete. In addition, these or other competitors may succeed in obtaining FDA and other regulatory clearances and approvals of their products more rapidly than us.

### **Government Regulation**

The manufacture and sale of our medical diagnostic devices is subject to extensive governmental regulation in the United States and in other countries where we sell our products. In addition, our research and development activities in the United States are subject to various health and safety, employment and other laws and regulations.

## *United States FDA Approval*

PrepStain and FocalPoint are regulated for cervical cytology applications in the United States as medical devices by the FDA under the FDC Act and require pre-market approval by the FDA prior to commercial distribution. In addition, certain modifications to the manufacturing process or labeling of medical devices are subject to FDA review and approval before marketing. Pursuant to the FDC Act, the FDA regulates the clinical testing, manufacture, labeling, distribution, sales, marketing, advertising and promotion of medical devices in the United States. Noncompliance with applicable requirements, including good clinical practice requirements, can result in the refusal of the government to grant pre-market approval for devices, suspension or withdrawal of clearances or approvals, total or partial suspension of production, distribution, sales and marketing, fines, injunctions, civil penalties, recall or seizure of products, and criminal prosecution of a company, its officers and employees.

Medical devices are classified into one of three classes, Class I, II or III, on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls (e.g., labeling and adherence to FDA-mandated quality system requirements, including QSR, and, in some cases, pre-market notification ("510(k)"). Class II devices are subject to general controls including, in most cases, pre-market notification, and to special controls (e.g., performance standards, patient registries and FDA guidelines). Generally, Class III devices are those that must receive pre-market approval by the FDA to ensure their safety and effectiveness (e.g., life-sustaining, life-supporting and implantable devices) and also include most devices that were not on the market before May 28, 1976, known as "new medical devices," and for which the FDA has not made a finding of "substantial equivalence" based on a pre-market notification. Class III devices usually require clinical testing that demonstrates the device is safe and effective, and must have FDA approval prior to marketing and distribution. The conduct of clinical studies is subject to FDA regulations, including requirements for institutional review board approval, informed consent, record keeping, and reporting. Our PrepStain and FocalPoint products, when intended for gynecological use, are regulated as Class III medical devices. In addition, the FDA has developed special rules for *in vitro* diagnostic devices, including restrictions on the sale and use of analyte specific reagents ("ASR's"). Products that we develop now and in the future may be subject to these and other applicable FDA regulations.

Device manufacturers are required to register their establishments and list their devices with the FDA and to provide periodic reports containing information on safety and effectiveness. The FDC Act requires that medical devices be manufactured in accordance with the FDA's QSR regulation. PrepStain and FocalPoint and any other products that we manufacture or distribute pursuant to an approved PMA application and any supplements, or pursuant to 510(k) clearances, or as ASR's, are and will be subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experience with the use of the device. We will continue to be inspected on a routine basis by the FDA for compliance with regulations with respect to manufacturing, testing, distribution, storage and control activities. We have established and maintain a system for tracking FocalPoint and PrepStain systems through the chain of distribution and conduct post-market surveillance. Product labeling and promotional activities are also subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. We, and our distributors may only promote products for their approved indications. If the FDA requires us to make modifications to our product labeling in the future, these changes may adversely affect our ability to market or sell PrepStain, FocalPoint or any of our other products.

In addition, the FDA's Medical Device Reporting regulations require medical device companies to provide information to the FDA whenever evidence reasonably suggests that a device may have caused or contributed to a death or serious injury. These regulations also apply if the device malfunctions and the device or a similar device sold by the company would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

If the FDA believes that we have not complied with the law, it can take one or more of the following actions:

- refuse to review or clear applications to market our products in the United States;
- refuse to allow us to enter into government supply contracts;
- withdraw approvals already granted;
- require that we notify users regarding newly found risks;
- request repair, refund or replacement of faulty devices;
- request corrective advertisements, recalls or temporary marketing suspension; or
- initiate legal proceedings to detain or seize products, enjoin future violations, or assess civil or criminal penalties against us, our officers or employees.

These actions could seriously disrupt our operations for an indefinite period of time.

#### *Environmental, Health, Safety and Other Regulations*

We also are subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. Our manufacturing activities involve the use, storage, handling and disposal of hazardous materials and chemicals and, as a result, we are required to comply with regulations and standards of the Occupational Safety and Health Act and other safety and environmental laws. Although we believe that our activities currently comply with all applicable laws and regulations, the risk of accidental contamination or injury cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result, which could have a material adverse effect on our business, financial condition and results of operations. Further, we can give no assurance that we will not be required to incur significant costs to comply with such laws and regulations in the future, or that such laws or regulations will not have a material adverse effect upon our business, financial condition and results of operations.

#### *Foreign Regulatory Approval*

Sales of medical devices outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. No assurance can be given that such foreign regulatory approvals will be granted on a timely basis, or at all. We have been advised by various parties, including consultants we engaged and foreign distributors, that no regulatory approvals for a device analogous to FDA approval of a PMA are currently required by any country where we currently sell PrepStain. Such approval requirements may be imposed in the future. In addition to regulatory approvals in the United States, the FocalPoint system is approved for primary screening and quality control re-screening in Japan, Canada, Australia, New Zealand, The Netherlands, Italy, Hong Kong, Korea, and Taiwan. In September 2001, we announced receipt of a Medical Device License in Canada to market both our PrepStain System (formerly the AutoCyte PREP System) and the PrepMate accessory. We intend to pursue additional product registrations in other foreign countries. We received an FDA permit to export PrepStain and FocalPoint to all foreign countries in which we are currently selling these products and where such a permit was required. There can be no assurance that we will meet the FDA's export requirements or receive additional FDA export approval when such approval is necessary, or that countries to which the devices are to be exported will approve the devices for import. Our failure to meet the FDA's export requirements or obtain FDA export approval when required to do so, or to obtain approval for import, could have a material adverse effect on our business, financial condition and results of operations.

Our products are subject to a variety of regulations in Europe, including the European Union. In vitro medical devices, including the FocalPoint System, must now comply with the EU's In-Vitro Diagnostic Medical Devices Directive. The Directive was published in the Official Journal of European Communities in

December 1998. The EU member states were required to implement the Directive into national law by December 1999. A transition period, which begins from the date of publication of the Directive and ends December 2003, applies to all devices placed on the market in the EU. During this transition period, both Directive CE-marked and non-CE-marked devices may be placed on the market. In other words, companies may choose to follow either the CE mark or the national legislation, if any. If no such national legislation exists, the devices can be freely placed on the market. By the end of this transition period, our products must comply with the requirements of the Directive and member-state local language requirements. At such time, products not bearing the CE mark may not be commercially distributed in European Union member countries. In addition, member states may continue to restrict or prohibit the marketing of CE-marked devices pursuant to the safeguard clause of the Directive if the member state determines a particular device may compromise the health and/or safety of patients or users. We intend to comply with the Directive and other applicable regulations in accordance with the requirements of the countries in which we market and sell our products.

Other European countries may enact national laws that would conform to the Directive. Member states of the EU and the European Economic Area may enact requirements in addition to those imposed by the Directive. Some European countries have established national regulations relating to in vitro diagnostic medical devices. EU directives and national laws impose requirements for electrical safety and electromagnetic compatibility that apply to the PrepStain System, PrepMate, and FocalPoint System. We have performed the requisite testing procedures and related documentation to apply the European CE mark to the FocalPoint, PrepStain and PrepMate systems. We cannot guarantee that the FocalPoint System or any other product we may develop will receive any required regulatory clearance or approval on a timely basis, if at all.

Congress has directed the Department of Health and Human Services to issue regulations designed to improve the quality of biomedical analytic services, particularly the examination of Pap smears. These regulations require clinical laboratories to randomly re-screen at least 10% of the Pap smears classified on initial manual screen as normal. This 10% must include normal cases selected from the laboratory's total caseload, and from patients or groups of patients that have a high probability of developing cervical cancer based on available patient information. The laboratories that would purchase our PrepStain and FocalPoint products, or our ASR's, are subject to extensive regulation under the Clinical Laboratory Improvement Act of 1988, as amended (CLIA), which requires laboratories to meet specified standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We believe that our PrepStain and FocalPoint products operate in a manner that will allow laboratories using our products to comply with CLIA requirements. However, there can be no assurance that interpretations of current CLIA regulations or future changes in CLIA regulations would not make compliance by the laboratory difficult or impossible and therefore have an adverse effect on sales of our products.

In addition, laboratories often must comply with state regulations, inspection, and licensing. In recent years, a few states, including New York and California, have adopted regulations that limit the number of slides that may be manually examined by a cytotechnologist within a given period of time. We cannot guarantee that states will not directly regulate FocalPoint in the future, nor can we predict the effect, if any, new regulations may have on our business or operations.

### **Product Liability**

Commercial use of any of our products may expose us to product liability claims. We currently maintain general liability and product liability insurance coverage and believe that the amount of such coverage is adequate to meet our present needs. The medical device industry has experienced increasing difficulty in obtaining and maintaining reasonable product liability coverage, and substantial increases in insurance premium costs in many cases have rendered coverage economically impractical. To date, we have not experienced difficulty obtaining an amount of insurance coverage commensurate with our level of sales. As our sales expand, however, there can be no assurance that our existing product liability insurance will be adequate or that additional product liability insurance will be available to us at a reasonable cost, or that any product

liability claim would not have a material adverse effect on our business, financial condition and results of operations.

### Employees

As of December 31, 2001, we employed approximately 200 people on a full-time basis. Additionally, we have contracted approximately 40 salespeople to sell our products through our arrangement with NPS. We believe that relations with our employees are good. None of our employees are party to a collective bargaining agreement.

### Item 1A. Executive Officers of the Registrant

Our current executive officers are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Paul R. Sohmer, M.D. ....	53	President, Chief Executive Officer and Chairman of the Board
Stephen P. Hall .....	51	Senior Vice-President, Chief Financial Officer
John G.R. Hurrell, Ph.D. ....	52	Senior Vice-President, TriPath Oncology
Ray W. Swanson .....	46	Senior Vice-President, Commercial Operations

*Paul R. Sohmer, M.D.* has served as our Chairman of the Board of Directors since November 2000, and as our President and Chief Executive Officer since June 2000. Prior to joining us, Dr. Sohmer served as the President and Chief Executive Officer of Neuromedical Systems, Inc. from 1997 through 1999. From 1996 until 1997, Dr. Sohmer served as President of a consulting firm which he founded. From 1993 to 1996, he served as President and Chief Executive Officer of Genetrix, Inc., a genetic services company based in Scottsdale, Arizona. From 1991 through 1993, Dr. Sohmer was the Corporate Vice-President of Professional Services and President of the Professional Services Organization for Nichols Institute, a clinical laboratory company, where he was responsible for sales, marketing, information systems, logistics, and clinical studies. From 1985 until 1991, Dr. Sohmer served as the President and Chief Executive Officer of Pathology Institute in Berkeley, California, during which time he founded and served as Medical Director of the Chiron Reference Laboratory. Dr. Sohmer received a B.A. degree from Northwestern University and an M.D. from Chicago Medical School.

*Stephen P. Hall, CPA* has served as our Senior Vice-President and Chief Financial Officer since September 2001. Prior to joining us, Mr. Hall served as Chief Financial Officer and President of the Imaging and Power System Division of Colorado Medtech, Inc., a Colorado-based medical products and services company, from September 1999 until August 2001. From September 1993 to January 1999, he served as Chief Financial Officer for BioTechnica International, Inc., a publicly held agricultural products company, as well as privately held operating companies in the software development, wireless communication equipment and food processing machinery industries. Mr. Hall spent nine years in the commercial banking industry and with the accounting firm of Peat, Marwick, Mitchell & Co. He earned a bachelors degree from Harvard College and an MBA from the Stanford Graduate School of Business.

*John G.R. Hurrell, Ph.D.* has served as Senior Vice-President of TriPath Oncology since December 2001. Prior to joining us, Dr. Hurrell served as Vice-President, Diagnostic Technology at Genzyme Corp., a biotechnology company in Cambridge, Massachusetts, from January 1995 to September 1996. From July 1989 to January 1995, he served as the Vice-President Molecular Diagnostics, Diagnostic Product Development, and Patient Care Systems at Boehringer Mannheim Corporation, a medical diagnostics company in the US. Prior to that, Dr. Hurrell served as the President, CEO, Director and Co-founder of FluorRx, Inc., a medical technology company in Carmel, Indiana, from September 1996 to June 2000. Immediately prior to joining TriPath, he served as the Chief Operating Officer and Head of Research and Development for Argose, Inc., a glucose monitoring company in Waltham, Massachusetts. Dr. Hurrell received his Ph.D. from the University of Melbourne and was a Fullbright Research Fellow at Harvard Medical School.

*Ray W. Swanson* has served as our Senior Vice President of Commercial Operations since May 2001. Prior to joining us, he served as General Manager of e-Business for Dade Behring, one of the world's largest clinical diagnostics companies. Mr. Swanson held a number of senior management positions at Dade Behring and its predecessor companies since 1987. From 1997 to 1999, he was the general manager responsible for the introduction and market development of Dade's platelet function business. As President of Dade's Japanese subsidiary from 1994 to 1997, he was a member of the management team that purchased Baxter International's diagnostics businesses and created Dade International as a privately held, stand-alone company. Prior to 1987, he held positions with Johnson and Johnson, American Hospital Supply Corporation, Solvay (a global chemical and pharmaceutical company) and Washington University School of Medicine's Department of Anatomy and Neurobiology. Mr. Swanson has B.S. and M.S. degrees in zoology from Eastern Illinois University and an MBA from the University of Iowa.

## **Item 2. Properties**

We currently lease a total of 43,000 square feet of space devoted to manufacturing, warehousing, administrative, research and development and engineering functions, at 780 Plantation Drive, Burlington, North Carolina under a seven-year lease expiring in July 2005. The lease is renewable for five additional one-year terms. We lease approximately 72,000 square feet of office and manufacturing space in Redmond, Washington under operating leases expiring in December 2004. Of this space in Redmond, we sublease approximately 30,000 square feet as sub-lessor. We also currently lease approximately 10,000 square feet to serve as educational and corporate office space at 1111 Huffman Mill Road in Burlington, North Carolina under a three-year lease expiring in June 2004. This facility lease contained an option to expand the leased space by 4,500 square feet, which we exercised in June 2001. We also lease office space in Brussels, Belgium, under an operating lease expiring in August 2007. We believe that our facilities and other available office space are adequate for our current needs.

We have signed a lease for the occupancy of approximately 22,000 square feet near the Research Triangle Park area, in Durham, North Carolina. When occupied in mid-2002, this space will be devoted primarily to the activities of TriPath Oncology. The lease has a seven-year term expiring in 2009.

## **Item 3. Legal Proceedings**

In the normal course of business, we are subject to various legal proceedings and claims.

On August 4, 2000, the Company and several other parties were named as defendants to a civil action commenced in the District Court of Tarrant County, Texas. The petition alleges that the defendants, including us, fraudulently induced the plaintiffs to retain their investment in NeoPath. A final judgment dismissing the claim with prejudice has been entered without any material liability to us.

## **Item 4. Submission of Matters to a Vote of Security Holders**

There were no matters submitted to a vote of security holders of the Company during the fourth quarter of the fiscal year ended December 31, 2001:

## PART II

### Item 5. Market for Registrant's Common Equity and Related Stockholder Matters

Our Common Stock, \$0.01 par value per share (the "Common Stock"), is traded on the Nasdaq National Market under the symbol "TPTH". The following table sets forth, for the calendar periods indicated, the range of high and low bid and ask prices for our Common Stock on the Nasdaq National Market. These prices do not include retail mark-up, mark-down or commissions and may not represent actual transactions.

	<u>High</u>	<u>Low</u>
<b>Year ended December 30, 2000:</b>		
First Quarter .....	\$14.125	\$3.750
Second Quarter .....	\$ 9.125	\$4.500
Third Quarter .....	\$11.125	\$4.563
Fourth Quarter .....	\$10.000	\$7.500
<b>Year ended December 30, 2001:</b>		
First Quarter .....	\$13.000	\$5.000
Second Quarter .....	\$12.490	\$2.900
Third Quarter .....	\$ 8.800	\$3.030
Fourth Quarter .....	\$ 8.190	\$4.000

On March 25, 2002, the last reported sales price of the Common Stock on the Nasdaq National Market was \$5.61 per share. As of March 25, 2002, there were 37,454,684 shares of our Common Stock outstanding, which were held by approximately 340 Common Stockholders of record.

#### Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain our future earnings, if any, for use in our business and therefore do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our Board of Directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion.

## Item 6. Selected Financial Data

The selected consolidated financial data presented below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes thereto included elsewhere in this Form 10-K.

	Year ended December 31,				
	1997	1998	1999	2000	2001
	(in thousands, except per share data)				
<b>Statement of Operations Data (3):</b>					
Net sales .....	\$ 13,492	\$ 16,849	\$ 18,466	\$ 32,652	\$ 27,017
Gross profit (loss) .....	6,765	7,155	8,098	16,646	14,070
Research and development (1) .....	18,711	15,969	12,258	9,351	8,534
Selling, general and administrative .....	24,278	25,408	17,724	24,263	28,220
Operating loss .....	(36,224)	(37,307)	(33,251)	(16,968)	(22,684)
Net loss .....	<u>\$(34,582)</u>	<u>\$(35,271)</u>	<u>\$(32,557)</u>	<u>\$(17,369)</u>	<u>\$(21,680)</u>
Net loss per Share (basic and diluted) (2) .....	<u>\$ (1.91)</u>	<u>\$ (1.46)</u>	<u>\$ (1.17)</u>	<u>\$ (0.60)</u>	<u>\$ (0.61)</u>
Weighted-average shares outstanding (3) .....	<u>18,123</u>	<u>24,098</u>	<u>27,819</u>	<u>29,137</u>	<u>35,467</u>

	Year ended December 31,				
	1997	1998	1999	2000	2001
	(in thousands)				
<b>Balance Sheet Data (3):</b>					
Cash, cash equivalents and short-term investments .....	\$57,374	\$28,941	\$13,962	\$54,340	\$55,976
Working capital .....	64,881	32,553	17,338	62,316	62,898
Total assets .....	95,962	68,176	58,874	97,471	96,748
Long term obligations .....	151	2,051	1,117	3,760	5,001
Total stockholders' equity .....	\$88,255	\$55,075	\$47,025	\$80,774	\$77,292

(1) Includes regulatory expenses.

(2) See Note 2 of Notes to our financial statements for information concerning the computation of net loss per share and shares used in computing net loss per share.

(3) The selected consolidated financial data has been restated to reflect the pooling transaction that occurred on September 30, 1999.

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with the Consolidated Financial Statements and Notes thereto included elsewhere in this Form 10-K.

### Background

We develop, manufacture, market, and sell proprietary products for cancer detection, diagnosis, staging, and treatment selection. We are using our proprietary technologies, and know-how to create an array of products designed to improve the clinical management of cancer. We were formed in September 1999 through the merger of AutoCyte, Inc. and NeoPath, Inc. and acquisition of the technology and intellectual property of Neuromedical Systems, Inc. We were created to leverage the complementary nature of the products, technologies, and intellectual property developed by our predecessor companies, all of whom were early pioneers in the application of computerized image processing and analysis to detect the often subtle cellular abnormalities associated with cancer and its precursors. To date, we have developed an integrated solution for cervical cancer screening and other products that deliver image management, data handling, and prognostic

tools for cell diagnosis, cytopathology and histopathology. We believe that recent advances in genomics, biology, and informatics are providing new opportunities and applications for our proprietary technology.

We are organized into two operating units:

- Commercial Operations, through which we manage the market introduction, sales, service, manufacturing, and ongoing development of our products; and
- TriPath Oncology, our wholly-owned subsidiary, through which we manage the development of molecular diagnostic and pharmacogenomic tests for cancer.

### *Commercial Operations*

During 2002, we adopted the trademark TriPath Care Technologies to describe our commercial product offering and to communicate the broad nature of our corporate vision and the value created by our growing product portfolio, including the "i<sup>3</sup>" series and SlideWizard product lines.

To further refine our market positioning and to enhance brand awareness among our customers, we have re-branded our cervical cancer screening products under the "i<sup>3</sup>" product line. Our "i<sup>3</sup>" series product line for screening for cervical cancer is the first integrated system for the collection, preparation, staining and computerized analysis of conventional Pap smears and liquid-based, thin-layer preparations. Our i<sup>3</sup> product line includes the:

- SurePath System, a proprietary, liquid-based cytology sample collection, preservation and transport system and PrepStain, an automated slide preparation system that produces slides with a standardized, thin layer of stained cervical cells, which together were formerly known as the AutoCyte PREP System ("PrepStain"). SurePath addresses errors in cell sample collection and slide preparation while providing a liquid medium for adjunctive laboratory testing of specimens, whereas the PrepStain Slide Processor reduces the complexity of interpretation by providing a homogeneous, more representative and standardized thin layer of stained cells and a liquid medium for adjunctive laboratory testing of specimens. The United States Food & Drug Administration ("FDA") approved PrepStain in June 1999.
- FocalPoint SlideProfiler System, a slide screening system that uses proprietary technology to distinguish between normal thin-layer or conventional Pap smears and those that have the highest likelihood of abnormality, formerly known as the AutoPap Primary Screening System ("FocalPoint"). In May 1998, FocalPoint was approved by the FDA as the first and only fully automated device for primary screening of conventional Pap smear slides. In October 2001, FocalPoint was further approved by the FDA to screen PrepStain processed thin-layer slides.

Our SlideWizard product line includes the Image Titer, an FDA cleared method for automating the measurement of antinuclear antibody, research applications for DNA, immunohistochemical quantification, cellular analysis, and expression quantification, a system for the transmission and interpretation of tissue specimens via remote telecommunications or "telepathology", and a software based storage and retrieval system for microscopic images.

### *PrepStain*

We generate PrepStain revenue from either the sale, rental or lease of PrepStain systems and from the sale of the related SurePath and PrepStain test kits, comprised of proprietary reagents and other disposables. Additionally, we generate revenue from service contracts on the PrepStain systems. For system sales, customers purchase the PrepStain instrument and make separate purchases of SurePath and PrepStain test kits. We recognize revenue on sales of the PrepStain system at the time the instrument is installed and accepted at the customer site. For system rentals, we place PrepStain systems at the customer's site free of charge and the customer is obligated to purchase SurePath and PrepStain test kits for a fixed term, typically three or four years. Under these transactions, there is no revenue recognized on the PrepStain system hardware. For system leases, we offer two alternatives. The first alternative involves a lease arrangement

directly through us for the PrepStain instrument and related hardware. These leases require monthly payments for the equipment and are typically for 36 or 48 month terms. The customer purchases the PrepStain reagents and disposables that run on the instruments separately from the lease on an as-needed basis. Under these transactions, there is no revenue recognized on the PrepStain system hardware. The second alternative is known as our IPO program, under which PrepStain systems are purchased by a third party financial institution and are placed at the customer's site free of charge. The customer then purchases the PrepStain reagents at a price that is sufficient to repay the financial institution for the cost of the PrepStain instrument and to provide us with an acceptable profit on the reagents and disposables. Under the IPO program, we record revenue for the instrument sale at the time the instrument is installed and accepted at the customer site. During 2001, our strategy was to emphasize system leases versus the IPO program for the instruments placed with customers and thereby retaining a greater percentage of our ongoing, higher margin PrepStain reagent revenue stream. However, regardless of whether PrepStain systems are sold, rented or leased, each system placed typically provides a recurring revenue stream as customers process our SurePath test kits.

#### *FocalPoint*

We generate FocalPoint related revenue from the direct sale of FocalPoint systems, and from the placement of FocalPoint systems under fee-per-use contracts. In the latter case, fee-per-use revenue commences in the month a system is initially placed in commercial use at a customer site and consists of per-slide monthly billings, fixed rental billings, or certain fee-per-use contracts that require minimum payments. Domestic customers may also elect to purchase the FocalPoint instrument under the IPO program. We have recently converted fee-per-use contracts to direct sale arrangements. Additionally, we generate revenue from service contracts on FocalPoint systems.

#### *SlideWizard*

We also generate revenue from either the sale or rental of our SlideWizard line of products and from service contracts on these products. For system sales, customers purchase the products through distributors in countries where such relationships exist. Where distributor arrangements do not exist, we sell these products directly to the customer.

We market our cervical screening products to domestic and foreign clinical laboratories through direct sales activities in the United States and primarily through distributors in international markets. In the fourth quarter of 2000, we significantly expanded our marketing and sales activities to accelerate the commercialization of our products. We hired additional laboratory sales representatives to increase contact potential for the laboratory customer marketplace. Through an alliance with NPS, we engaged the physician market directly for the first time by adding physician directed representatives, on a contract basis, to augment our direct sales efforts. To further educate and reinforce the benefits of our cervical cancer screening products, we initiated a partnership with a third party physician/peer selling organization that will continue into 2002. In addition, we entered into an agreement with a third-party financial institution to support the placement of PrepStain systems that are leased under our Integrated Purchase Option, or "IPO" program, and FocalPoint fee-per-use systems to help maximize the number of instruments placed with customers and thereby increase our ongoing, higher margin PrepStain reagent and fee-per-use revenue streams. As a result of these efforts, we anticipate that manufacturing and marketing expenses will increase to the extent that market acceptance of our products increases.

#### **Oncology Business**

Our TriPath Oncology business focuses on developing and commercializing molecular diagnostic and pharmacogenomic tests for a variety of cancers. On July 31, 2001, we entered into a series of agreements with Becton, Dickinson and Company ("BD") to develop and commercialize molecular diagnostics and pharmacogenomic tests for malignant melanoma and cancers of the cervix, breast, ovary, colon and prostate as part of the ongoing strategic alliance between BD and Millennium Pharmaceuticals, Inc. ("Millennium").

The goal of our molecular oncology program is to utilize discoveries in genomics and proteomics research to develop and commercialize diagnostic and pharmacogenomic tests to improve the clinical management of cancer. Specifically, we have active programs in development designed to identify individuals with cancer at the earliest possible stage of the disease, provide individualized predictive and prognostic information, guide treatment selection for patients with cancer, and predict disease recurrence. The core products and services we are developing through our collaboration with BD will be based upon genomic and proteomic markers identified through discovery research, conducted at Millennium, under its existing research and development agreement with BD. TriPath Oncology will clinically validate and develop these proprietary cancer markers into commercial diagnostic and pharmacogenomic oncology products and services. Commercial responsibilities for resulting products will be shared between BD and TriPath Oncology. BD will continue to fund additional discovery research activities at Millennium.

TriPath Oncology is not expected to generate any significant revenue until 2004. Consequently, the Oncology business unit will incur expenses in excess of revenues generated. We anticipate that by the latter half of 2002, TriPath Oncology will incur approximately \$1.0 million in incremental expense per month. A portion of these expenses include the lease of a portion of BD's facility in Research Triangle Park, North Carolina. Total rent paid to BD was \$5,087 during 2001. This arrangement will end during 2002 after TriPath Oncology's laboratory space is completed, which is expected in mid-2002.

Our future revenues and the results of operations may change significantly from quarter to quarter and will depend on many factors, including:

- our product research and development and clinical trial activities and projected expenditures;
- the extent to which our products gain market acceptance;
- the timing and volume of system placements;
- pricing of competitive products;
- the cost and effect of promotional discounts, sales, and marketing programs and strategies;
- introduction of alternative technologies by our competitors;
- regulatory and reimbursement matters, including the complexities of clinical studies;
- FDA approval of our new products in development;
- ability to negotiate licenses where required;
- the ability of collaborators to fulfill their obligations under agreements; and
- the extent to which we are successful in developing research and marketing alliances.

We believe that our intellectual property portfolio provides a strong foundation for the development and defense of imaging products. We also believe that recent advances in genomics, biology, and informatics, in addition to our collaboration with BD, will continue to provide new opportunities to leverage our proprietary technology. To date, we have used our technology to develop an integrated solution for cervical cancer screening and other products for the histopathology laboratory. Through our collaboration with BD, we will further develop our technology for molecular diagnostic applications for various cancers.

### **Critical Accounting Policies**

The United States Securities and Exchange Commission ("SEC") recently issued disclosure guidance requesting that registrants describe their "critical accounting policies." The SEC defines "critical accounting policies" as those that are both important to the description of our financial condition and results of operations and require application of management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods.

Our significant accounting policies are described in Note 2 in the Notes to Consolidated Financial Statements, which have been prepared in accordance with generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to sales of our products, bad debts, inventories, investments, intangible assets, warranty obligations, and legal issues. Since not all of these accounting policies require management to make difficult, subjective or complex judgments or estimates, they are not all considered critical accounting policies. However, we believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

#### *Revenue Recognition*

We record revenue from either the sale, rental or lease of our systems and from the sale of related consumables. Additionally, we record revenue from service contracts on our systems. Revenue recognition on system sales occurs at the time the instrument is installed and accepted at the customer site. For system rentals, systems are placed at the customer's site free of charge and the customer is obligated either to purchase test kits for a fixed term, or are charged fees based on monthly minimum, or actual, usage. Under these transactions, there is no capital equipment revenue recognized. We also offer leasing alternatives. Under these transactions, we may, or may not, recognize revenue on system hardware depending on the particular details of the lease.

#### *Allowance for Doubtful Accounts Receivable*

We continuously monitor payments from our customers and maintain allowances for doubtful accounts receivable for estimated losses resulting from the inability of our customers to make required payments. When we evaluate the adequacy of our allowances for doubtful accounts, we take into account various factors including our accounts receivable aging, customer credit-worthiness, historical bad debts and current economic trends. We are closely monitoring several delinquent accounts with past due balances outstanding, and will continue to do so, to determine the need, if any, to further increase our allowance for doubtful accounts receivable. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required. At December 31, 2001 and 2000, our accounts receivable balance was \$9.6 million and \$11.5 million, respectively.

#### *Inventory*

Inventory is stated at the lower of cost or net realizable value. Cost is based on a first-in, first-out basis. If cost is less than net realizable value, then cost is used for inventory valuation. If we determine that net realizable value is less than cost, then we write down the related inventory to market value. We review net realizable value of inventory in detail on an on-going basis, with consideration given to deterioration, obsolescence, and other factors. If actual market conditions are less favorable than those projected by management, and our estimates prove to be inaccurate, additional write-downs or adjustments to recognize additional cost of goods for overstated inventory may be required. At December 31, 2001 and 2000, our inventory balance was \$10.7 million and \$8.4 million, respectively.

#### *Valuation of long-lived and intangible assets*

We review the value of our long-lived assets, including goodwill, for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. If we determine that the carrying value of intangibles, long-lived assets and related goodwill may not be recoverable based upon one or more indicators of impairment, the asset is written down to its estimated fair value based on a discounted cash flow basis. During 2001, we recognized \$430,000 of such a loss for the placement of certain Customer-Use Assets free of charge at a customer under a two-year contract.

## Results of Operations

*Years ended December 31, 2001 and 2000*

**Revenue** — Revenues for the year ended December 31, 2001 were \$27.0 million, a 17.3% decrease from revenues of \$32.7 million for 2000. Sales related to the SurePath and PrepStain systems increased \$5.3 million, or 16.2%, from 2000 to 2001. Consumable sales increased \$5.2 million, or 90.3%. Revenues related to the FocalPoint declined by \$11.1 million, or 33.9%, for the same period. Other revenue, including sales of our SlideWizard products and revenue recorded under service agreements increased \$99,000, or 3.2% between 2000 and 2001.

In 2001, we shifted our sales and marketing efforts to drive the sales of our SurePath and PrepStain systems and their associated higher margin reagent and disposable products. We implemented a series of management actions that we believe are reflected in the revenues recorded for the year and will impact on our future revenue performance. First, we expanded our sales and marketing team to approximately 110 sales and marketing professionals, including 40 who were contracted through NPS to provide detail selling to ordering physicians. Second, we revised our sales incentive programs to promote reagent sales. Third, we sought to build a "franchise" among academic centers of excellence and successfully added high profile, opinion leaders to our customer list. Fourth, we actively encouraged the presentation and publication in refereed journals of independent investigators' experience with our SurePath and PrepStain products. In excess of 40 papers were published or presented at international and national meetings regarding the performance of our products. Fifth, we directed our sales organization to target laboratories whose increased test volumes provide greater opportunity for repeat reagent sales. Sixth, we focused on the placement of new PrepStain instruments under reagent rental arrangements and in-house lease arrangements rather than IPO third party leasing programs which historically had been the financing mechanism utilized by the majority of our customers. In the short term, this resulted in reduced revenue recorded from up front capital equipment sales associated with the IPO program. We believe, however, that reductions of capital equipment sales associated with the IPO arrangements will result in an increase in the average unit sales price for SurePath and PrepStain related disposables. Seventh, we gained FDA approval for the PrepMate accessory to our PrepStain system in May 2001; and for FocalPoint screening of SurePath thin-layer slides in October 2001; and we announced receipt of a Medical Device License in Canada to market both our PrepStain System and the PrepMate accessory.

The decline in FocalPoint related revenues from 2000 to 2001 represented a \$9.1 million decline in fee-per-use revenues and a \$2.0 million decline in instrument sales. We believe that this decline in FocalPoint related revenue can be attributed to several factors. First, we believe that much of the decline resulted from the ongoing U.S. market shift toward liquid-based Pap testing, since the FocalPoint was not FDA approved to screen SurePath thin-layer slides until the fourth quarter of 2001 and, therefore, could only be used for the screening of conventional Pap smears in the U.S. for most of the year. The decline in the number of tests performed on the FocalPoint corresponded with the general decline in conventional Pap smear testing in the U.S. in 2001. Subsequent to receiving FDA approval in October of 2001, we have leveraged the combined product to drive sales of reagents and disposables. We expect to realize the results from this action in 2002 and beyond. Second, FocalPoint revenues declined due to completion of our arrangement with Quest Diagnostics who signed an exclusive agreement for liquid based thin-layer testing products with a competitor in 2000. Third, as described above, as we awaited FDA approval to screen SurePath slides with the FocalPoint, we shifted our sales focus to drive our higher margin reagent and disposable business.

**Gross Margin** — Gross margin improved slightly from 51.0% in 2000 to 52.1% in 2001. Contributing to the improvement in 2001 was increased sales of SurePath and PrepStain test kits for gynecological purposes.

**Research and Development** — Research and development expenses include salaries and benefits of scientific and engineering personnel, testing equipment, relevant consulting and professional services, components for prototypes and certain facility costs. Research and development expenses for 2001 were \$6.7 million, a 22.5% decrease from \$8.6 million in 2000. This decrease was primarily attributable to reduced professional fees incurred in 2001. Included in research and development expenses in 2001 were \$408,000 of expenses related to our subsidiary, TriPath Oncology, which we established to carry out the research, development and

commercialization efforts stemming from our agreement with BD. These expenses related to TriPath Oncology also reflect \$1.0 million of amortization, against expense, of a deferred research and development credit arising out of the accounting for this transaction. We accounted for this transaction in accordance with Statement of Financial Accounting Standard No. 68, "Research and Development Arrangements". We began amortizing the credit in August 2001 and will continue the amortization over 30 months at \$206,600 per month against research and development expenses.

*Regulatory* — Regulatory expenses include salaries and benefits of regulatory and quality personnel, costs related to clinical studies and submissions to the FDA, and relevant consulting services. Regulatory expenses for the year ended December 31, 2001 were \$1.9 million, representing a 146.6% increase from \$761,000 in 2000. This change was primarily attributable to the rebuilding and refocusing of our regulatory efforts, which began in the third quarter ended September 30, 2000, and to the regulatory efforts surrounding our FDA submissions, specifically those concerning FDA approval of the use of FocalPoint to process thin-layer slides prepared with PrepStain, and upcoming clinical studies.

*Sales and Marketing* — Sales and marketing expenses include salaries and benefits of sales, marketing, sales support and service personnel, and their related expenses, as well as non-personnel-related expenses related to marketing our products. Sales and marketing expenses for the year ended December 31, 2001 were \$18.3 million, including \$220,000 of expenses related to TriPath Oncology. This represented a 235.4% increase from \$5.5 million in 2000. This increase is primarily due to our efforts to significantly expand our sales and marketing capabilities, including the addition of various employees and initiatives focused on product management and brand identification. We dramatically increased our sales and marketing staff to over 100 people by the end of 2001.

*General and Administrative* — General and administrative expenses include salaries and benefits for administrative personnel, legal and other professional fees and certain facility costs. General and administrative expenses, including the provision for doubtful accounts receivable of \$1.8 million, and approximately \$673,000 of expenses attributable to TriPath Oncology, for the year ended December 31, 2001 were \$9.9 million, representing a 47.4% decrease from \$18.8 million in 2000. This decrease is primarily due to one-time, non-cash compensation charges of \$2.1 million related to repricing of stock options in 2000 and decreased legal costs, and related charges in 2001.

*Net Loss from Operations* — Net loss from operations during 2001 was \$22.7 million, a 33.7% increase from \$17.0 million in 2000. This increase is due to reduced gross profit, of \$2.6 million, resulting from the 17.3% decrease in revenue coupled with increased operating expenses of \$3.1 million, or 9.3%.

*Interest Income and Expense* — Interest income for 2001 was \$2.3 million, an 84.8% increase from \$1.3 million during 2000, primarily attributable to increased average cash balances during 2001 in spite of declining interest rates throughout 2001. The higher average cash balances resulted from a cash payment of \$25.0 million from an investment in our Common Stock by BD during the third quarter of 2001 and 43.0 million from an investment by Roche in our Common Stock in the fourth quarter of 2000. Interest expense for 2001 was \$1.3 million compared to \$1.7 million during 2000. This decrease is due to reduced balances outstanding resulting from principal repayments under our debt facilities.

#### *Years ended December 31, 2000 and 1999*

*Revenue* — Revenues for the year ended December 31, 2000 were \$32.7 million, a 76.8% increase from revenue of \$18.5 million for 1999. The increase in revenues is attributable to increases of \$6.9 million in sales of FocalPoint and PrepStain instruments. FocalPoint instrument sales increased \$5.2 million, or 156.3% between years while sales of PrepStain instruments increased \$1.7 million, or 87.4%. Sales of PrepStain consumables and revenue recorded under usage arrangements increased \$5.6 million, or 47.3% between 1999 and 2000. Contributing to the increase was increased sales of the PrepStain reagents and consumables of \$3.5 million, or 158.1% and increased sales under fee-per use and other usage arrangements of \$2.1 million, or 21.5%. Other revenue, including sales of our SlideWizard products and revenue recorded under service agreements increased \$1.7 million, or 119.8% between periods.

*Gross Margin* — Gross margin increased from 43.9% in 1999 to 51.0% in 2000. Contributing substantially to the increase in 2000 was increased PREP disposables revenue for gynecological purposes.

*Research and Development* — Research and development expenses include salaries and benefits of scientific and engineering personnel, testing equipment, relevant consulting and professional services, components for prototypes and certain facility costs. Research and development expenses for 2000 were \$8.6 million, a 23.5% decrease from \$11.2 million in 1999. This decrease was primarily attributable to the elimination of redundant research and development efforts after the AutoCyte/NeoPath merger.

*Regulatory* — Regulatory expenses include salaries and benefits of regulatory and quality personnel, costs related to clinical studies and submissions to the FDA, and relevant consulting services. Regulatory expenses for the year ended December 31, 2000 were \$761,000, representing a 26.4% decrease from \$1.0 million in 1999. This change was primarily attributable to reductions in expenses associated with our FDA submission related to our PrepStain liquid-based product, which received approval during 1999, and to initial reduced redundant costs resulting from the merger of AutoCyte and NeoPath in 1999.

*Sales and Marketing* — Sales and marketing expenses include salaries and benefits of sales, marketing, sales support and service personnel, and their related expenses, as well as non-personnel-related expenses related to marketing our products. Sales and marketing expenses for 2000 were \$5.5 million, a 36.9% increase from \$4.0 million in 1999. This increase resulted from new sales and marketing programs focused on commercializing our FDA approved products.

*General and Administrative* — General and administrative expenses include salaries and benefits for administrative personnel, legal and other professional fees and certain facility costs. General and administrative expenses for the year ended December 31, 2000 were \$18.8 million, representing a 36.9% increase from \$13.7 million in 1999. This increase is primarily due to one-time, non-cash compensation charges related to repricing of stock options in 2000 and increased legal costs, offset in part by the elimination of certain redundant general and administrative expenses after the AutoCyte/NeoPath merger.

*Net Loss from Operations* — Net loss from operations during 2000 was \$17.0 million, a 49.0% improvement from \$33.3 million in 1999. This improvement is due to improved gross profit resulting in large part from the 76.8% increase in revenues that was partially offset by an increase in selling, general and administrative expenses. A reduction in research and development and regulatory expenses of \$2.9 million, as well as approximately \$11.4 million in costs related to the AutoCyte/NeoPath merger, also contributed to the improvement.

*Interest Income and Expense* — Interest income for 2000 was \$1.3 million, a 13.1% increase from \$1.1 million during 1999, primarily attributable to increased average cash balances during 2000 coupled with higher average rates of return on funds invested. The higher average cash balances resulted from cash received from an investment by Roche during the fourth quarter of 2000 and from a term loan we acquired in the first quarter of 2000. Interest expense for 2000 was \$1.7 million compared to \$416,000 during 1999. This increase is due to a term loan facility entered into during 2000.

#### **Recently Issued Accounting Standards**

In July 2001, the Financial Accounting Standards Board ("FASB") issued SFAS No. 141, "Business Combinations" and SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 141 requires that all business combinations be accounted for under the purchase method only and that certain acquired intangible assets in a business combination be recognized as assets apart from goodwill. SFAS No. 142 requires that ratable amortization of goodwill be replaced with periodic tests of the goodwill's impairment and that intangible assets other than goodwill be amortized over their useful lives. SFAS No. 141 is effective for all business combinations initiated after June 30, 2001 and for all business combinations accounted for by the purchase method for which the date of acquisition is after June 30, 2001. The provisions of SFAS No. 142 will be effective for fiscal years beginning after December 15, 2001. As required, we will adopt SFAS No. 142 in fiscal year 2002. We do not expect any significant impact from the adoption of SFAS No. 141 and SFAS No. 142 on our financial statements.

In August 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations." SFAS 143 requires an entity to record a liability for an obligation associated with the retirement of an asset at the time that the liability is incurred by capitalizing the cost as part of the carrying value of the related asset and depreciating it over the remaining useful life of that asset. The standard is effective for us beginning January 1, 2003. We do not expect the adoption of SFAS No. 143 to have a material impact on our results of operations or financial condition.

In August 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. The objectives of SFAS 144 are to address significant issues relating to the implementation of SFAS No. 121 (SFAS 121), *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of*, and to develop a single accounting model, based on the framework established in SFAS 121, for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired. SFAS 144 is effective for financial statements issued for fiscal years beginning after December 15, 2001 and, generally, its provisions are to be applied prospectively. We do not expect the adoption of SFAS 144 to have a significant impact on us.

### **Liquidity and Capital Resources**

Since our formation, our expenses have significantly exceeded our revenues, resulting in an accumulated deficit of \$206.4 million as of December 31, 2001. We have funded our operations primarily through the private placement and public sale of equity securities, debt facilities and limited product sales resulting in cumulative net proceeds of \$216.6 million as of December 31, 2001. We had cash, cash equivalents and short-term investments of \$56.0 million at December 31, 2001.

Cash used in our operations was \$19.0 million in 2001, \$8.2 million during 2000 and \$23.0 million during 1999. Negative operating cash flow during 2001, 2000, and 1999 was caused primarily by operating losses. Our capital expenditures were \$936,000 in 2001, \$217,000 in 2000, and \$516,000 during 1999 with expenditures primarily attributable to the purchase of machinery and equipment. We have no material commitments for capital expenditures.

We recorded \$1.8 million to bad debt expense in 2001, compared with \$220,000 and \$816,000 in 2000 and 1999, respectively. During 2001, we experienced a slowing of collections on several international accounts receivable, in large part attributable to an overall slowdown in the world economy. We continue to monitor these international accounts receivable and believe that, based on communications with these customers, and partial payments received during the year, that the accounts receivable reserve recorded is adequate to cover any losses that may be realized.

During 2000 and 2001, the declining interest rates in the U.S. impacted amounts earned on our invested funds. Average yields on invested funds have fallen between 450 and 500 basis points, on average. This is contrary to the fixed-rate nature of our borrowings and other term debt. If this interest rate environment continues, there will be a net negative impact on our cash relative to net interest income.

We had \$2.5 million of short-term investments at December 31, 2001. The investments are part of a managed portfolio of excess cash we have to invest. Our short-term investments have a maturity of more than three months, but less than one year when purchased and are stated at cost. Management intends to hold these investments to maturity.

On February 8, 2000, we entered into a \$7.0 million subordinated term loan with a syndicate of lenders to finance operations. We drew \$5.3 million of this facility in February 2000 and the balance of \$1.7 million in March 2000. We have remaining amounts outstanding under this loan of approximately \$3.6 million at December 31, 2001. This loan will be fully amortized and repaid during the first quarter of 2003. At the present time, we have no plans to replace that loan with a similar facility after it is repaid.

In February 2001, we renewed a \$5.0 million working capital facility with a bank. The outstanding balance is limited to an amount equal to 80% of eligible accounts receivable. The line commitment expired on January 31, 2002 and was renewed for an additional year until January 31, 2003. The line bears interest at the bank's prime rate plus 1/2% and is collateralized by substantially all of our assets. The line of credit carries

customary covenants, including the maintenance of a minimum modified quick ratio and other requirements. We had no outstanding borrowings under this agreement at December 31, 2001 though the availability under the line of credit could provide additional funding if needed. We have no other long-term debt commitments and no off-balance sheet financing vehicles.

We accrued a long-term contingent liability, at December 31, 2000, in the amount of \$1.3 million in accordance with the provisions of SFAS No. 5, "Accounting for Contingencies," relating to our obligation to pay a third party an amount based on the difference between the market price of the Common Stock on a specified date in the future and a predetermined target price. The balance of this contingent liability was \$1.5 million at December 31, 2001.

On July 31, 2001, we completed a private placement of securities under Regulation D of the Securities Act with BD pursuant to which BD acquired 2,500,000 shares of our Common Stock for \$10.00 per share. The transaction with BD provided us with an additional \$25.0 million in cash. Additionally, a wholly-owned subsidiary of Millennium simultaneously acquired 400,000 shares of our Common Stock in consideration of entering into a research license with us. We also paid \$1.0 million in connection with other aspects of the transaction.

In connection with our collaboration with BD, we assumed the operations of BD Gene, BD's research and development endeavor in the molecular diagnostics arena. The products developed by TriPath Oncology will be based upon the genomic discovery research, conducted at Millennium, under its existing research and development agreement with BD. TriPath Oncology and BD will configure validated markers provided by Millennium, under its agreement with BD, into commercial diagnostic and pharmacogenomic products and services. Commercial responsibilities for resulting products will be shared between BD and TriPath Oncology. TriPath Oncology is not expected to generate any significant revenue until 2004. Consequently, this segment of our business will incur expenses in excess of revenue generated. It is anticipated that by the latter half of 2002, TriPath Oncology will incrementally incur approximately \$1.0 million of expense per month.

We believe that our existing cash and anticipated additional debt and/or lease financing for internal use assets, rental placements of PrepStain and fee-per-use placements of FocalPoint, will be sufficient to enable us to meet our future cash obligations for at least the next twelve months.

Our future liquidity and capital requirements will depend on a number of factors, including:

- the level of placements of both PrepStain and FocalPoint systems;
- demand for our combined PrepStain and FocalPoint systems for cervical cancer screening and of FocalPoint GS in the United States, if and when it gains FDA approval;
- the resources required to further develop our marketing and sales capabilities domestically and internationally, and the success of those efforts;
- the resources required to expand manufacturing capacity;
- TriPath Oncology's ability to develop and commercialize products through our collaboration with BD; and
- the extent to which our products gain market acceptance.

We anticipate that marketing and sales expenditures for the continued SurePath commercial rollout for gynecological uses in the United States, capital expenditures associated with placements of PrepStain IPO and rental units and FocalPoint fee-per-use instruments, and expenditures related to manufacturing, TriPath Oncology and other administrative costs, will increase significantly. If our existing resources are insufficient to satisfy our liquidity requirements, we may need to raise additional funds through bank facilities, the sale of additional equity or debt securities or other sources of capital. The sale of any equity or debt securities may result in additional dilution to our stockholders, and we cannot be certain that additional financing will be available in amounts or on terms acceptable to us, if at all. Additional funding may not be available when needed or on terms acceptable to us, which would have a material adverse effect on our liquidity and capital resources, business, financial condition and results of operations.

## **Income Taxes and Tax Loss Carryforwards**

We have not generated any taxable income to date and, therefore, have not paid any federal income taxes since inception. Realization of deferred tax assets is dependent on future earnings, if any, the timing and amount of which are uncertain. Accordingly, we have established valuation allowances, in amounts equal to the net deferred tax assets as of December 31, 2001 and 2000, in each period to reflect these uncertainties.

At December 31, 2001, we had net tax losses of approximately \$181.5 million that may be carried forward to offset future taxable income. In addition, we had research credits available for carryforward of \$3.4 million. These amounts begin to expire in 2003. Utilization of net tax losses and any tax credit carryforwards are subject to complex treatment under the Internal Revenue Code of 1986, as amended (the "Code"). Pursuant to Section 382 of the Code, the change in ownership resulting from our initial public offering in September 1997 and any other future sale of stock may limit utilization of future losses in any one year. We believe that the sale of Common Stock in the offering did not create any immediate limitations on our utilization of net operating losses.

## **Factors Affecting Future Operations and Results**

The discussion included in this section, as well as elsewhere in the Annual Report on Form 10-K, may contain forward-looking statements based on current expectations of our management. These forward-looking statements appear principally in the sections entitled "Business" and "Management's Discussion and Analysis of Financial Conditions and Results of Operations." Generally, the forward-looking statements in this report use words like "expect," "believe," "continue," "anticipate," "estimate," "may," "will," "could," "opportunity," "future," "project," and similar expressions. Such statements are subject to risks and uncertainties that could cause actual results to differ from those projected. The forward-looking statements include statements about our:

- projected timetables for the preclinical and clinical development of, regulatory submissions and approvals for, and market introduction of our products and services;
- estimates of the potential markets for our products and services;
- sales and marketing plans;
- assessments of competitors and potential competitors;
- estimates of the capacity of manufacturing and other facilities to support our products and services;
- expected future revenues, operations and expenditures; and
- projected cash needs.

Statements that are not historical facts are based on our current expectations, beliefs, assumptions, estimates, forecasts and projections for our business and the industry and markets in which we compete. The forward-looking statements contained in this report are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. We caution investors not to place undue reliance on the forward-looking statements contained in this report, which speak only as the date hereof. We undertake no obligation to update these statements to reflect events or circumstances occurring after the date of this report or to reflect the occurrence of unanticipated events, except as required by law.

The following factors, among others, create risks and uncertainties that could affect our future or other performance:

- our ability to successfully commercialize the diagnostic oncology products and services developed by TriPath Oncology;
- our dependence on the collaboration with BD, any changes in its business direction or priorities or defaults in its or Millennium's obligations which may have an adverse impact on our product development efforts;

- market acceptance of our products and services;
- our history of operating losses and our expectation that we will incur significant additional operating losses;
- any inability to raise the capital that we will need to sustain our operations;
- our ability to establish and maintain licenses, strategic collaborations and distribution arrangements;
- our ability to manufacture sufficient amounts of our products for development and commercialization activities;
- our dependence on limited source suppliers for key components of our cervical screening products;
- our limited marketing and sales resources;
- difficulties in managing our growth;
- our ability to obtain and maintain adequate patent and other proprietary rights protection of our products and services;
- time consuming and expensive proceedings to obtain, enforce or defend patents and to defend against charges of infringement that may result in unfavorable outcomes and could limit our patent rights and our activities;
- significant fluctuations in our revenues and operating results, which have occurred in the past and which we expect to continue to fluctuate in the future;
- risks associated with international sales and operations and collaborations;
- our common stock may continue to have a volatile public trading price and low trading volume;
- anti-takeover provisions in our governing documents and under Delaware law and our shareholder rights plan that may make an acquisition of us more difficult
- competition and technological change that may make our potential products and technologies less attractive or obsolete;
- failure to acquire technology and integrate complementary businesses;
- our ability to obtain reimbursement for our products and services from third-party payers; and
- any loss or inability to hire and retain qualified personnel;

As a result of the foregoing and other factors, we may experience material fluctuations in our future operating results, which could materially affect our business, financial position, and stock price. These risks and uncertainties are discussed in more detail in Exhibit 99.1 "Factors Affecting Future Operating Results" to this Form 10-K, which is incorporated into this item by this reference.

#### **Item 7A. Quantitative and Qualitative Disclosure About Market Risk**

We do not participate in derivative financial instruments, other financial instruments for which the fair value disclosure would be required under SFAS No. 107, or derivative commodity instruments. All of our investments are in short-term, investment-grade commercial paper, corporate bonds and U.S. Government and agency securities that are carried at fair value on our books. Accordingly, we have no quantitative information concerning the market risk of participating in such investments.

Our primary market risk exposures are in the areas of interest rate risk and foreign currency exchange rate risk. Our financial results and cash flows are subject to fluctuation due to changes in interest rates, primarily from our investment of available cash balances in highly rated institutions. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. See *Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* under *Liquidity and Capital Resources* for further discussion of the impact of interest rates on our financial results.

We operate in several foreign countries and are subject to fluctuations in foreign currencies to a minor extent. We have no foreign exchange contracts, option contracts, or other foreign hedging arrangements. However, the impact of fluctuations in foreign currencies on our financial results has not been material and are unlikely to have a material adverse effect on our business, financial condition or results of operations in the future.

**Item 8. Financial Statements and Supplementary Data**

The information required by this item may be found on pages F-1 through F-22 of this Form 10-K.

**Item 9. Changes In and Disagreements with Accountants on Accounting and Financial Disclosure**

There have been no changes in or disagreements with accountants on accounting or financial disclosure matters in the last fiscal year.

**PART III**

**Item 10. Directors and Executive Officers of the Registrant**

The response to this item is contained in part under the caption "Executive Officers of the Registrant" in Part I, Item 1A hereof and the remainder is incorporated herein by reference from the discussion responsive thereto under the captions "Election of Directors" and "Section 16(a) Beneficial Reporting Compliance" in our Proxy Statement relating to our Annual Meeting of Stockholders scheduled for May 23, 2002 (the "Proxy Statement").

**Item 11. Executive Compensation**

The response to this item is incorporated herein by reference from the discussion responsive thereto under the captions "Election of Directors," "Director Compensation," "Executive Compensation" and "Compensation Committee Interlocks, Insider Participation and Certain Transactions" in the Proxy Statement.

**Item 12. Security Ownership of Certain Beneficial Owners and Management**

The response to this item is incorporated herein by reference from the discussion responsive thereto under the caption "Share Ownership" in the Proxy Statement.

**Item 13. Certain Relationships and Related Transactions**

The response to this item is incorporated herein by reference from the discussion responsive thereto under the caption "Compensation Committee Interlocks, Insider Participation and Certain Transactions" in the Proxy Statement. See also Note 11 to the Consolidated Financial Statements included herewith.

**PART IV**

**Item 14. Exhibits, Financial Statement Schedules and Reports on Form 8-K**

(a) 1. *Financial Statements*

The consolidated financial statements are listed under Part II, Item 8 of this report.

2. *Financial Statement Schedule*

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the accompanying Consolidated Financial Statements.

3. *Exhibits*

The exhibits are listed under Part IV, Item 14(c) of this report.

(b) *Reports on Form 8-K*

On October 30, 2001, we filed a Form 8-K to include information on our receipt of approval from the United States Food & Drug Administration to include the screening of PrepStain (formerly, AutoCyte® PREP) thin-layer slide preparation on the FocalPoint Slide Profiler (formerly, AutoPap® Primary Screening System).

On March 29, 2002, we filed a Form 8-K to include information regarding a correction to our earnings for the year ended December 31, 2001 related to a change in the amount of interest expense recorded related to amortization of non-cash debt issuance costs under a term loan agreement

(c) *Exhibits*

- 2.1 Agreement and Plan of Merger dated June 4, 1999 among AutoCyte, Trilogy Acquisition Corp. and NeoPath, Inc. Filed as Exhibit 2.1 to our Form 8-K (File No. 333-30227) filed on June 23, 1999 and incorporated herein by reference
- 3.1 Restated Certificate of Incorporation of the Company. Filed as Exhibit 3.5 to our Registration Statement on Form S-1 (File No. 333-30227) and incorporated herein by reference
- 3.2 Amended and Restated By-laws of the Company. Filed as Exhibit 3.7 to our Registration Statement on Form S-1 (File No. 333-30227) and incorporated herein by reference
- 4.1 Specimen of Common Stock Certificate. Filed as Exhibit 4.1 to our Registration Statement on Form S-1 (File No. 333-30227) and incorporated herein by reference
- 10.1\* Amended and Restated 1996 Equity Incentive Plan (including forms of incentive stock option certificate and nonstatutory stock option certificate). Filed as Exhibit 10.1 to our Registration Statement on Form S-1 (File No. 333-30227) and incorporated herein by reference
- 10.2\* 1997 Director Stock Option Plan (including form of director nonstatutory stock option certificate). Filed as Exhibit 10.2 to our Registration Statement on Form S-1 (File No. 333-30227) and incorporated herein by reference
- 10.3† OEM Supply Agreement dated January 13, 1995 between Tecan AG and RIAS, the Company's predecessor. Filed as Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-30227) and incorporated herein by reference
- 10.4† Amendment to the OEM Supply Agreement dated October 14, 1996 between Tecan AG and RIAS, the Company's predecessor. Filed as Exhibit 10.7 to the Company's Registration Statement on Form S-1 (File No. 333-30227) and incorporated herein by reference
- 10.5 Contribution Agreement dated as of November 22, 1996 by and among HLR Holdings Inc., RIAS and the Company. Filed as Exhibit 10.10 to the Company's Registration Statement on Form S-1 (File No. 333-30227) and incorporated herein by reference
- 10.6\* Form of Indemnification Agreement between the Company and its Directors and Executive Officers. Filed as Exhibit 10.11 to the Company's Registration Statement on Form S-1 (File No. 333-30227) and incorporated herein by reference
- 10.7 Lease Agreement dated as of July 28, 1997 by and between Carolina Hosiery Mills, Inc. and the Company. Filed as Exhibit 10.12 to the Company's Registration Statement on Form S-1 (File No. 333-30227) and incorporated herein by reference
- 10.8 Lease Agreement dated June 12, 1998 by and between Carolina Hosiery Mills, Inc. and AutoCyte, Inc. Filed as Exhibit 10.1 to the Company's Form 10-Q for the quarter ended June 30, 1998 (File No. 0-22885) and incorporated herein by reference
- 10.9† Supply Agreement dated March 5, 1998 by and between Tecan AG and AutoCyte, Inc. Filed as Exhibit 10.3 to the Company's Form 10-Q for the quarter ended June 30, 1998 (File No. 0-22885) and incorporated herein by reference

- 10.10 Master Loan and Security Agreement dated December 21, 1998 by and between Oxford Venture Finance, LLC and AutoCyte, Inc. Filed as Exhibit 10.17 to the Company's Form 10-K for the year ended December 31, 1998 (File No. 0-22885) and incorporated herein by reference
- 10.11 Amendment dated March 2, 1999 to Lease Agreement dated July 28, 1997 by and between Carolina Hosiery Mills, Inc. and AutoCyte, Inc. Filed as Exhibit 10.1 to the Company's Form 10-Q for the quarter ended March 31, 1999 (File No. 0-22885) and incorporated herein by reference
- 10.12 Asset Purchase Agreement by and between AutoCyte, Inc. and Neuromedical Systems, Inc. dated as of March 25, 1999. Filed as Exhibit 10.2 to the Company's Form 10-Q for the quarter ended March 31, 1999 (File No. 0-22885) and incorporated herein by reference
- 10.13 Intellectual Property Purchase Agreement dated as of April 24, 1999 by and between NeoPath, Inc. and AutoCyte, Inc. Filed as Exhibit 10.21 to the Amendment No. 2 to the Company's S-1 (File No. 333-82121) and incorporated herein by reference
- 10.14† Master Agreement dated as of November 18, 1999 by and between TriPath Imaging, Inc. and Laboratory Corporation of America Holdings. Filed as Exhibit 10.22 to the Company's Form 10-K for the year ended December 31, 1999 (File No. 0-22885) and incorporated herein by reference
- 10.15 Loan and Security Agreement dated as of January 19, 2000 by and between MMC/GATX Partnership No. I, Transamerica Business Credit Corporation and TriPath Imaging, Inc. Filed as Exhibit 10.1 to the Company's Form 10-Q for the quarter ended March 31, 2000 (File No. 0-22885) and incorporated herein by reference
- 10.16 Loan and Security Agreement dated as of January 31, 2000 (the "Loan and Security Agreement") by and between Silicon Valley Bank and TriPath Imaging, Inc. Filed as Exhibit 10.2 to the Company's Form 10-Q for the quarter ended March 31, 2000 (File No. 0-22885) and incorporated herein by reference
- 10.17 Securities Purchase Agreement, dated September 26, 2000, by and among TriPath Imaging, Inc., Roche International Ltd. and Certain Stockholders of TriPath Imaging. Filed as Exhibit 99.2 to the Company's Form 8-K as filed with the commission on October 24, 2000 (File No. 0-232885) and incorporated herein by reference
- 10.18 Securities Purchase Agreement dated as of July 31, 2001 by and between the Company and Becton, Dickinson and Company. Filed as Exhibit 10.1 to the Company's Form 10-Q for the quarter ended June 30, 2001 (File No. 0-22885) and incorporated herein by reference
- 10.19 Securities Purchase Agreement dated as of July 31, 2001 by and among the Company, Millennium Pharmaceuticals, Inc. and mHoldings Trust. Filed as Exhibit 10.2 to the Company's Form 10-Q for the quarter ended June 30, 2001 (File No. 0-22885) and incorporated herein by reference
- 10.20 License and Intellectual Property Access Agreement dated as of July 31, 2001 by and between the Company and Becton, Dickinson and Company. Filed as Exhibit 10.3 to the Company's Form 10-Q for the quarter ended June 30, 2001 (File No. 0-22885) and incorporated herein by reference
- 10.21 Development and License Agreement dated as of July 31, 2001 by and among the Company, Becton, Dickinson and Company and TriPath Oncology, Inc. Filed as Exhibit 10.4 to the Company's Form 10-Q for the quarter ended June 30, 2001 (File No. 0-22885) and incorporated herein by reference
- 10.22 Sublicense Agreement dated as of July 31, 2001 by and among the Company, Becton, Dickinson and Company and TriPath Oncology, Inc. Filed as Exhibit 10.5 to the Company's Form 10-Q for the quarter ended June 30, 2001 (File No. 0-22885) and incorporated herein by reference
- 10.23 Transitional Services Agreement dated as of July 31, 2001 by and among the Company, Becton, Dickinson and Company and TriPath Oncology, Inc. Filed as Exhibit 10.6 to the Company's Form 10-Q for the quarter ended June 30, 2001 (File No. 0-22885) and incorporated herein by reference

- 10.24 Option Agreement dated as of July 31, 2001 by and between the Company and Becton, Dickinson and Company. Filed as Exhibit 10.7 to the Company's Form 10-Q for the quarter ended June 30, 2001 (File No. 0-22885) and incorporated herein by reference
- 10.25 Lease Agreement between NeoPath, Inc. and Teachers Insurance & Annuity Association dated October 1, 1994 (the "Lease Agreement") and all amendments thereto. Filed herewith
- 10.26 Sublease Agreement by and between NeoPath, Inc. and Antioch Bible Church dated as of August 31, 1999. Filed herewith
- 10.27 Assignment of the Lease Agreement from NeoPath, Inc. to AutoCyte, Inc. dated September 28, 1999. Filed herewith
- 10.28† OEM Supply Agreement dated November 1, 2001 by and between Tecan Schweiz AG and the Company. Filed herewith
- 10.29 Amendment dated December 1, 2001 to Lease Agreement dated June 12, 1998 by and between Carolina Hosiery Mills, Inc. and TriPath Imaging, Inc. Filed herewith
- 10.30 Second Loan Modification Agreement to the Loan and Security Agreement effective as of January 31, 2002 by and between Silicon Valley Bank and TriPath Imaging, Inc. Filed herewith
- 10.31 Lease Agreement dated as of February 6, 2002 by and between TBC Place Partners II, LLC and TriPath Oncology, Inc. Filed herewith
- 21.1 List of all subsidiaries of the Company. Filed herewith
- 23.1 Consent of Ernst & Young LLP, independent auditors to the Company. Filed herewith
- 99.1 Factors Affecting Future Operating Results. Filed herewith

\* Indicates a management contract or compensatory plan.

† Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission pursuant to both Rule 406 of the Securities Act of 1933, as amended, and Rule 24b-2 of the Securities Exchange Act of 1934, as amended, as applicable. Omitted information is identified with asterisks in the appropriate places in the agreement.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Burlington, State of North Carolina, on March 29, 2002.

TRIPATH IMAGING, INC.

By: /s/ PAUL R. SOHMER  
Paul R. Sohmer, M.D.  
Chairman, President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on this 29th day of March, 2002.

<u>Signature</u>	<u>Title</u>
<u>/s/ PAUL R. SOHMER</u> Paul R. Sohmer, M. D.	President, Chief Executive Officer and Director (Principal Executive Officer)
<u>/s/ STEPHEN P. HALL</u> Stephen P. Hall	Senior Vice-President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
<u>/s/ THOMAS A. BONFIGLIO</u> Thomas A. Bonfiglio, M.D.	Director
<u>/s/ RICHARD A. CHARPIE</u> Richard A. Charpie	Director
<u>/s/ HAYWOOD D. COCHRANE, JR.</u> Haywood D. Cochrane, Jr.	Director
<u>/s/ ROBERT E. CURRY</u> Robert E. Curry	Director
<u>/s/ DAVID A. THOMPSON</u> David A. Thompson	Director

TRIPATH IMAGING, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
Report of Independent Auditors .....	F-2
Consolidated Balance Sheets as of December 31, 2001, and 2000 .....	F-3
Consolidated Statements of Operations for the Years Ended December 31, 2001, 2000, and 1999 ...	F-4
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2001, 2000, and 1999 .....	F-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 2001, 2000, and 1999 ..	F-6
Notes to Consolidated Financial Statements .....	F-7

## REPORT OF INDEPENDENT AUDITORS

The Board of Directors and Stockholders  
TriPath Imaging, Inc.

We have audited the accompanying consolidated balance sheets of TriPath Imaging, Inc. and subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of TriPath Imaging, Inc. and subsidiaries at December 31, 2001 and 2000, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

Raleigh, North Carolina  
January 25, 2002

**TRIPATH IMAGING, INC.**  
**CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2001	2000
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 53,476,920	\$ 54,340,169
Short-term investments .....	2,498,692	—
Accounts receivable, less allowance of \$3,284,531 and \$1,475,000 at December 31, 2001 and 2000, respectively .....	9,580,744	11,548,974
Inventory, less reserves for obsolescence of \$2,311,654 and \$2,338,573 at December 31, 2001 and 2000, respectively .....	10,717,960	8,422,184
Other current assets .....	1,079,197	940,692
Total current assets .....	77,353,513	75,252,019
Customer use assets, net .....	6,088,726	9,399,739
Property and equipment, net .....	2,362,642	1,868,059
Other assets .....	916,445	107,242
Patents, less accumulated amortization of \$1,751,911 and \$1,085,165 at December 31, 2001 and 2000, respectively .....	7,792,507	8,459,253
Goodwill, less accumulated amortization of \$765,625 and \$615,625 at December 31, 2001 and 2000, respectively .....	2,234,375	2,384,375
Total assets .....	\$ 96,748,208	\$ 97,470,687
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 4,411,541	\$ 4,600,312
Accrued expenses .....	4,115,547	3,947,111
Deferred revenue and customer deposits .....	729,587	1,156,541
Deferred research and development funding .....	2,479,200	—
Current portion of long-term debt .....	2,719,781	3,232,114
Total current liabilities .....	14,455,656	12,936,078
Long-term debt, less current portion .....	790,196	2,447,594
Other long-term liabilities .....	4,210,400	1,312,789
Stockholders' equity:		
Preferred stock, \$0.01 par value; 1,000,000 shares authorized; none issued and outstanding .....	—	—
Common stock, \$0.01 par value; 49,000,000 shares authorized; 37,304,738 and 34,125,649 shares issued and outstanding at December 31, 2001 and 2000, respectively .....	373,047	341,256
Additional paid-in capital .....	283,395,526	265,260,039
Deferred compensation .....	—	(89,140)
Accumulated deficit .....	(206,417,624)	(184,737,929)
Accumulated other comprehensive loss .....	(58,993)	—
Total stockholders' equity .....	77,291,956	80,774,226
Total liabilities and stockholders' equity .....	\$ 96,748,208	\$ 97,470,687

See accompanying notes

**TRIPATH IMAGING, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Year Ended December 31,		
	2001	2000	1999
Revenues .....	\$ 27,017,066	\$ 32,651,749	\$ 18,465,774
Cost of revenues .....	12,946,717	16,006,248	10,368,173
Gross profit .....	14,070,349	16,645,501	8,097,601
Operating expenses:			
Research and development .....	6,658,163	8,590,040	11,224,364
Regulatory .....	1,875,683	760,729	1,033,725
Sales and marketing .....	18,333,360	5,466,069	3,993,217
General and administrative .....	9,887,392	18,796,431	13,730,354
Transaction, integration & restructuring costs .....	—	—	8,445,343
In-process research & development .....	—	—	2,922,000
	<u>36,754,598</u>	<u>33,613,269</u>	<u>41,349,003</u>
Operating loss .....	(22,684,249)	(16,967,768)	(33,251,402)
Interest income .....	2,321,183	1,256,359	1,110,627
Interest expense, including amortization of non-cash debt issuance costs under term loan agreement .....	(1,316,629)	(1,658,047)	(416,065)
Net loss .....	<u>\$(21,679,695)</u>	<u>\$(17,369,456)</u>	<u>\$(32,556,840)</u>
Net loss per common share (basic and diluted) .....	<u>\$ (0.61)</u>	<u>\$ (0.60)</u>	<u>\$ (1.17)</u>
Weighted-average common shares outstanding .....	<u>35,467,408</u>	<u>29,137,224</u>	<u>27,818,600</u>

See accompanying notes

TRIPATH IMAGING, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock	Additional Paid-in Capital	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income(Loss)	Total Stockholders' Equity
Balance at January 1, 1999	\$241,929	\$191,540,956	\$(1,880,516)	\$(134,811,633)	\$ (15,731)	\$ 55,075,005
Exercise of options and warrants	2,146	150,125	—	—	—	152,271
Private issuance of common stock	22,919	14,098,336	—	—	—	14,121,255
Issuance of common stock for intellectual property	14,000	9,335,917	—	—	—	9,349,917
Issuance of common stock under employee stock purchase plan	80	46,689	—	—	—	46,769
Issuance of stock based compensation to consultant	—	7,100	—	—	—	7,100
Adjustment to deferred compensation	—	(286,731)	286,731	—	—	—
Amortization of deferred compensation	—	—	814,140	—	—	814,140
Unrealized appreciation on securities available-for-sale	—	—	—	—	15,731	15,731
Net loss	—	—	—	(32,556,840)	—	(32,556,840)
Comprehensive loss	—	—	—	—	—	(32,541,109)
Balance at December 31, 1999	281,074	214,892,392	(779,645)	(167,368,473)	—	47,025,348
Exercise of options and warrants	8,382	1,542,762	—	—	—	1,551,144
Private issuance of common stock and warrants	50,000	42,950,000	—	—	—	43,000,000
Issuance of warrants as consideration under term loan agreement	—	1,725,041	—	—	—	1,725,041
Re-pricing of warrants issued as consideration under term loan agreement	—	420,042	—	—	—	420,042
Re-pricing of stock options	—	2,133,839	—	—	—	2,133,839
Issuance of stock based compensation	1,800	1,618,200	—	—	—	1,620,000
Adjustment to deferred compensation	—	(22,237)	22,237	—	—	—
Amortization of deferred compensation	—	—	668,268	—	—	668,268
Net loss	—	—	—	(17,369,456)	—	(17,369,456)
Comprehensive loss	—	—	—	—	—	(17,369,456)
Balance at December 31, 2000	341,256	265,260,039	(89,140)	(184,737,929)	—	80,774,226
Exercise of options and warrants	2,791	934,369	—	—	—	937,160
Private issuance of common stock	29,000	17,777,000	—	—	—	17,806,000
Re-pricing of warrants issued as consideration under term loan agreement	—	(575,882)	—	—	—	(575,882)
Amortization of deferred compensation	—	—	89,140	—	—	89,140
Foreign currency translation	—	—	—	—	(58,993)	(58,993)
Net loss	—	—	—	(21,679,695)	—	(21,679,695)
Comprehensive loss	—	—	—	—	—	(21,738,688)
Balance at December 31, 2001	\$373,047	\$283,395,526	\$ —	\$(206,417,624)	\$ (58,993)	\$ 77,291,956

See accompanying notes.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2001	2000	1999
<b>OPERATING ACTIVITIES</b>			
Net loss	\$(21,679,695)	\$(17,369,456)	\$(32,556,840)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	3,071,237	5,867,594	6,894,994
Amortization of intangible assets	816,746	816,745	604,081
Amortization of deferred compensation	89,140	668,268	814,140
Non-cash restructuring costs	—	—	4,239,489
Non-cash equity compensation	—	2,133,839	—
Purchased in-process research and development	—	—	2,922,000
Issuance of stock options for services rendered	—	—	7,100
Issuance of stock based compensation	—	1,620,000	—
Amortization of deferred research and development	(1,033,000)	—	—
Amortization of non-cash debt issuance costs	487,318	506,842	—
(Gain) loss on disposal of fixed assets	(9,300)	1,190	—
Other non-cash items	694,600	1,260,000	22,455
Changes in operating assets and liabilities:			
Accounts receivable	2,005,017	(6,160,002)	(1,836,385)
Inventory	(2,134,576)	1,327,825	(4,677,607)
Other current assets	(218,063)	(24,566)	(169,833)
Other long-term assets	(809,203)	187,089	619,519
Accounts payable and accrued expenses	99,962	1,444,355	(547,360)
Deferred revenue and customer deposits	(426,954)	(519,639)	713,510
Net cash used in operating activities	(19,046,771)	(8,239,916)	(22,950,737)
<b>INVESTING ACTIVITIES</b>			
Purchases of property and equipment	(935,683)	(217,493)	(515,825)
Disposals of property and equipment	9,300	—	—
Purchases of securities available-for-sale	—	—	(7,199,372)
Purchases of short-term investments	(2,498,692)	—	—
Maturities of securities available-for-sale	—	—	10,589,652
Additions to intellectual property	—	(17,260)	(4,259,797)
Other	106,323	—	—
Net cash used in investing activities	(3,318,752)	(234,753)	(1,385,342)
<b>FINANCING ACTIVITIES</b>			
Net proceeds from issuance of common stock and warrants	17,806,000	43,000,000	14,411,255
Issuance of common stock under employee stock purchase plan	—	—	46,769
Proceeds from exercise of stock options and warrants	937,160	1,551,144	152,271
Other	(41,022)	(79,218)	(220,020)
Proceeds from research and development agreement	6,198,000	—	—
Proceeds from long-term debt	—	8,500,000	1,242,565
Payments on long-term debt	(3,292,204)	(4,119,425)	(2,900,398)
Net cash provided by financing activities	21,607,934	48,852,501	12,732,442
Effect of exchange rate changes on cash	(105,660)	—	—
Net (decrease) increase in cash and cash equivalents	(863,249)	40,377,832	(11,603,637)
Cash and cash equivalents at beginning of period	54,340,169	13,962,337	25,565,974
Cash and cash equivalents at end of period	<u>\$ 53,476,920</u>	<u>\$ 54,340,169</u>	<u>\$ 13,962,337</u>
<b>SUPPLEMENTAL CASH FLOW INFORMATION</b>			
Cash paid for interest	\$ 829,311	\$ 1,151,205	\$ 416,065
<b>NONCASH INVESTING AND FINANCING ACTIVITIES</b>			
Issuance of warrants as consideration under term loan agreement and subsequent re-pricing	\$ (575,882)	\$ 2,145,083	\$ —
Common stock issued for acquisition of intellectual property	—	—	9,450,000
	<u>\$ (575,882)</u>	<u>\$ 2,145,083</u>	<u>\$ 9,450,000</u>

See accompanying notes.

## TRIPATH IMAGING, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. The Company

TriPath Imaging, Inc. ("TriPath" or the "Company"), formerly known as AutoCyte, Inc. ("AutoCyte"), develops, manufactures and markets products to improve cancer screening. The Company operates in two business segments: Commercial Operations, which centers its efforts on cervical cancer screening and TriPath Oncology, which is focused on the development of molecular diagnostic and pharmacogenomic tests for malignant melanoma and cancer of the prostate, breast, ovary, cervix and colon.

The Company's Commercial Operations business segment delivers improved slide-preparation technology through the PrepStain Slide Preparation System ("PrepStain"), formerly known as the AutoCyte PREP System<sup>TM</sup> ("PREP"), a proprietary automated thin-layer cytology sample preparation system that produces representative slides with a homogeneous, thin-layer of cervical cells, and is one of only two sample preparation systems approved by the U.S. Food and Drug Administration ("FDA") as a replacement for the conventional Pap smear. This segment also delivers visual intelligence technology to increase accuracy and productivity in medical testing through the FocalPoint Primary Screening System ("FocalPoint"), formerly known as the AutoPap<sup>®</sup> Primary Screening System ("AutoPap"), which utilizes proprietary technology to distinguish between normal Pap smears and those that have the highest likelihood of abnormality.

The TriPath Oncology segment was formed on July 31, 2001 when the Company entered into a series of agreements with Becton, Dickinson and Company ("BD") to develop and commercialize molecular diagnostics and pharmacogenomic tests for cancer as part of the ongoing strategic alliance between BD and Millennium Pharmaceuticals, Inc. ("Millennium"). In connection with its agreements with BD, the Company established TriPath Oncology, Inc. ("TriPath Oncology"), a wholly-owned subsidiary of the Company to manage its activities for this development and commercialization effort. TriPath Oncology will develop molecular diagnostic and pharmacogenomic tests for malignant melanoma and cancer of the prostate, breast, ovary, cervix and colon. These products will be based upon the genomic discovery research, conducted at Millennium, under its existing research and development agreement with BD. TriPath Oncology and BD will configure validated markers provided by Millennium, under its agreement with BD, into commercial diagnostic and pharmacogenomic products and services. Commercial responsibilities for resulting products will be shared between BD and TriPath Oncology.

Information on the Company's operations by segment and geographic area is included in Note 10.

#### *Historical Information*

On September 30, 1999, AutoCyte completed its merger of NeoPath, Inc. ("NeoPath") in exchange for approximately 13.8 million shares of AutoCyte common stock. The transaction was structured as a merger (the "Merger") of a wholly-owned subsidiary of AutoCyte with and into NeoPath. The Merger was a tax-free reorganization and was accounted for as a pooling of interests in accordance with Accounting Principles Board ("APB") Opinion No. 16, "Business Combinations". NeoPath developed and marketed products to increase accuracy in medical testing. In conjunction with the Merger, AutoCyte changed its name to TriPath Imaging, Inc.

**TRIPATH IMAGING, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

The results of operations for the separate companies and the combined amounts presented in the consolidated financial statements follow:

	<u>Nine Months Ended September 30, 1999</u> (unaudited)
<b>Revenues</b>	
AutoCyte .....	\$ 3,882,442
NeoPath .....	<u>8,203,803</u>
Combined .....	<u>\$12,086,245</u>
<b>Net Loss</b>	
AutoCyte .....	\$14,419,778
NeoPath .....	<u>15,092,893</u>
Combined .....	<u>\$29,512,671</u>

The accompanying consolidated financial statements include operations of the combined companies for all periods presented.

On March 25, 1999, TriPath entered into a purchase and sale agreement to acquire the intellectual property estate of Neuromedical Systems, Inc. ("NSI"), a developer of interactive, neural net technology for the computer screening of conventional Pap smears. The purchase was completed in May, 1999. This intellectual property estate is held by AutoCyte NC, LLC, a wholly-owned subsidiary of the Company.

Revenues from sales of products have not generated sufficient cash to fully support the Company's operations. The Company has incurred substantial losses since inception. The Company has funded its operations primarily through the private placement and public sale of equity securities, debt and lease financing, and product sales. The Company continues to be subject to certain risks and uncertainties common to early stage medical device companies including the uncertainty of availability of additional financing, extensive government regulation, uncertainty of market acceptance of its products, limited manufacturing, marketing and sales experience and uncertainty of future profitability.

**2. Significant Accounting Policies**

*Critical Accounting Policies*

For a discussion of the Company's Critical Accounting Policies, see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" of this document.

*Principles of Consolidation*

The consolidated financial statements include the accounts of TriPath and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

*Use of Estimates*

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

## TRIPATH IMAGING, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### *Reclassifications*

Certain amounts for the prior years have been reclassified to conform to the 2001 presentation. Such reclassifications had no impact on previously reported net earnings or financial position.

#### *Revenue Recognition*

Revenue is recognized from product sales and fee-per-use arrangements, including service and license agreements, rental contracts, and minimum fee-per-use contracts. The Company recognizes product sales revenue upon shipment if the products do not require installation at the customer's site upon shipment (typically international distributor sales and disposable sales). Fee-per-use and all service-related revenue is recognized as earned.

#### *Cash and Cash Equivalents*

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents.

#### *Short-term Investments*

Short-term investments have a maturity of more than three months, but less than one year when purchased and are stated at cost, which approximates market value.

#### *Inventory*

Inventory is stated at the lower of cost or net realizable value (first-in first-out basis). Net realizable value of inventory is reviewed in detail on an on-going basis, with consideration given to deterioration, obsolescence, and other factors.

#### *Customer-Use Assets*

PrepStain and FocalPoint systems manufactured for rental or fee-per-use placements are carried in inventory until the systems are shipped, at which time they are reclassified to customer-use assets (non-current assets). Reclassifications of \$418,143, \$2,142,642 and \$4,348,709 occurred between customer-use assets, property and equipment and inventory during 2001, 2000 and 1999, respectively. Customer-use assets are depreciated on a straight-line basis over an estimated useful life of four years. Depreciation expense of customer-use assets amounted to \$1,850,127, \$4,183,849 and \$4,065,233 during 2001, 2000 and 1999, respectively.

#### *Property and Equipment*

Property and equipment is stated at cost. Depreciation is computed using the straight-line method over the estimated useful lives (three to seven years) of the individual assets. Depreciation expense of property and equipment amounted to \$943,219, \$1,488,205 and \$2,829,761 during 2001, 2000 and 1999, respectively.

#### *Goodwill*

The excess cost over the fair value of net assets acquired ("goodwill") was historically amortized using the straight-line method over 20 years (See also "Recently Issued Accounting Standards" below).

## TRIPATH IMAGING, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### *Patents*

Patents consist of patents and core technology acquired from NSI. Such assets are amortized using the straight-line method over estimated useful lives ranging from 14 to 20 years (See also "Recently Issued Accounting Standards" below).

#### *Asset Impairment*

The Company periodically reviews the value of its long-lived assets to determine if an impairment has occurred. In accordance with Financial Accounting Standards Board ("FASB") Statement of Financial Accounting Standards ("SFAS") No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of", if this review indicates that the assets will not be recoverable, as determined based on an analysis of undiscounted cash flows over the remaining amortization period, the Company would reduce the carrying value of its long-lived assets accordingly. During 2001, the Company recognized \$430,000 of such a loss for the placement of certain Customer-Use Assets free of charge at a customer under a two-year contract. There were no such losses recognized in 1999 or 2000.

#### *Deferred Revenue*

Deferred revenue consists of up-front cash receipts related to FocalPoint and PrepStain service and equipment contracts and a worldwide exclusive international distributor agreement for the Company's ImageTiter® product. Pursuant to the terms of an agreement related to the ImageTiter product, the Company received a \$1,000,000 non-refundable payment for the agreement, services to be performed, and as a payment for future product shipments. Revenue related to the worldwide exclusive international distributor agreement is recognized ratably over four years. The balance remaining to be recognized as revenue amounted to \$50,995 and \$150,995 at December 31, 2001 and 2000, respectively. Revenue related to service and equipment contracts is recognized as earned.

#### *Income Taxes*

The Company accounts for income taxes using the liability method in accordance with SFAS No. 109, "Accounting for Income Taxes". Under the liability method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities.

#### *Research and Development Costs*

Research and development costs are charged to operations as incurred.

#### *Stock Based Compensation*

The Company accounts for stock options issued to employees in accordance with APB Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"). Under APB 25, no compensation expense is recognized for stock or stock options issued with an exercise price equivalent to the fair value of the Company's Common Stock. For stock options granted at exercise prices below the deemed fair value, the Company records deferred compensation expense for the difference between the exercise price of the shares and the deemed fair value. Any resulting deferred compensation expense is amortized ratably over the vesting period of the individual options.

Effective July 1, 2000, the FASB issued Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation" ("FIN 44"). FIN 44 provides guidance on issues regarding the application of APB 25. The Company has adopted the guidance provided by FIN 44 with effect from July 1, 2000. The Company recorded non-cash equity compensation expense of \$2.1 million for the 2000 year in accordance with the requirements of APB 25 and FIN44. There were no such expenses recognized in 2001.

## TRIPATH IMAGING, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

In October 1995, the FASB issued SFAS No. 123, "Accounting for Stock Based Compensation" ("SFAS 123"). For companies that continue to account for stock based compensation arrangements under APB 25, SFAS 123 requires disclosure of the pro forma effect on net income (loss) and earnings (loss) per share as if the fair value based method prescribed by SFAS 123 had been applied. The Company has adopted the pro forma disclosure requirements of SFAS 123 (See Note 8).

#### *Net Loss Per Common Share*

The Company incurred losses during all periods presented. As a result, the effect of options and warrants is anti-dilutive. Accordingly, there is no difference between basic and diluted loss per share.

#### *Advertising Expense*

The cost of advertising is expensed as incurred. Advertising and marketing expense, including trade show expense, amounted to \$1,333,210, \$314,034 and \$240,662 during 2001, 2000 and 1999, respectively.

#### *Foreign Currency Translation*

The financial statements of foreign subsidiaries and branches have been translated into U.S. dollars in accordance with SFAS No. 52, "Foreign Currency Translation". All balance sheet accounts have been translated using the exchange rates in effect at the balance sheet date. Income statement amounts have been translated using the average exchange rate for the year. The gains and losses resulting from the changes in exchange rates were immaterial in 1999 and 2000. In 2001 the loss has been reported in other comprehensive loss. The effect on the consolidated statements of operations of transaction gains and losses is insignificant for all years presented.

#### *Comprehensive Loss*

The Company adopted SFAS No. 130, "Reporting Comprehensive Income" ("SFAS 130") effective January 1, 1998. SFAS 130 requires the Company to display an amount representing comprehensive income (loss) for the year in a financial statement which is displayed with the same prominence as other financial statements. The Company has elected to present this information in the Statement of Stockholders' Equity.

#### *Concentration of Credit Risk*

The Company's principal financial instruments subject to potential concentration of credit risk are cash, cash equivalents, short-term investments, accounts receivable, and notes receivable. The Company invests its funds in highly rated institutions, and limits its investment in any individual debtor. The Company provides an allowance for doubtful accounts equal to the estimated losses to be incurred in the collection of accounts and notes receivable.

#### *Derivative Financial Instruments*

As of January 1, 2001, the Company adopted SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133"), which was issued in June 1998, and its amendments, SFAS No. 137, "Accounting for Derivative Instruments and Hedging Activities - Deferral of the Effective Date of FASB Statement No. 133" and SFAS No. 138, "Accounting for Derivative Instruments and Certain Hedging Activities" issued in June 1999 and June 2000, respectively (collectively referred to as SFAS 133). SFAS 133 establishes a comprehensive and consistent standard for the recognition and measurement of derivatives and hedging activities. The application of the new rules has not had a significant impact on the Company's consolidated financial position or results from operations.

TRIPATH IMAGING, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

*Recently Issued Accounting Standards*

In July 2001, the FASB issued SFAS No. 141, "Business Combinations" ("SFAS 141") and SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"). SFAS 141 requires that all business combinations be accounted for under the purchase method only and that certain acquired intangible assets in a business combination be recognized as assets apart from goodwill. SFAS 142 requires that ratable amortization of goodwill be replaced with periodic tests of the goodwill's impairment and that intangible assets other than goodwill be amortized over their useful lives. SFAS 141 is effective for all business combinations initiated after June 30, 2001 and for all business combinations accounted for by the purchase method for which the date of acquisition is after June 30, 2001. The provisions of SFAS 142 will be effective for fiscal years beginning after December 15, 2001, and will thus be adopted by the Company, as required, in fiscal year 2002. The Company does not expect any significant impact from the adoption of SFAS 142 on the Company's financial statements. The Company will continue to amortize patents as noted above, but the ratable amortization of goodwill will cease effective January 1, 2002. The Company recognized \$150,000 in goodwill amortization expense in each period presented.

In August 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations." SFAS 143 requires an entity to record a liability for an obligation associated with the retirement of an asset at the time that the liability is incurred by capitalizing the cost as part of the carrying value of the related asset and depreciating it over the remaining useful life of that asset. The standard is effective for the Company beginning January 1, 2003. The Company does not expect the adoption of SFAS No. 143 to have a material impact on the Company's results of operations or financial position.

In August 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144"), which superseded SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of" ("SFAS 121"). SFAS 144 removes goodwill from its scope, thus eliminating the SFAS 121 requirement to allocate goodwill to long-lived assets to be tested for impairment. The accounting for goodwill is now subject to SFAS 141 and SFAS 142. The provisions of SFAS 144 will be effective for fiscal years beginning after December 15, 2001, and will thus be adopted by the Company, as required, in fiscal year 2002. The Company does not expect any significant impact from the adoption of SFAS No. 144 on the Company's financial statements.

**TRIPATH IMAGING, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**3. Balance Sheet Information**

Select detailed balance sheet information is as follows:

	December 31,	
	2001	2000
<b>Accounts receivable</b>		
Trade accounts receivable .....	\$ 7,462,373	\$ 8,405,208
Current portion of notes receivable .....	1,780,517	422,596
Other accounts receivable .....	337,854	2,721,170
	\$ 9,580,744	\$11,548,974
<b>Inventory</b>		
Raw materials .....	\$ 7,442,310	\$ 3,438,601
Work-in-process .....	274,883	1,468,691
Finished goods .....	3,000,767	3,514,892
	\$10,717,960	\$ 8,422,184
<b>Customer-use assets</b>		
Customer-use systems .....	\$11,976,266	\$18,868,025
Accumulated depreciation .....	(5,887,540)	(9,468,286)
	\$ 6,088,726	\$ 9,399,739
<b>Property and equipment</b>		
Machinery and equipment .....	\$ 5,988,646	\$ 5,582,896
Demonstration equipment .....	771,241	754,470
Furniture, fixtures and improvements .....	1,198,797	1,100,581
Leasehold improvements .....	1,318,189	1,315,156
Vehicles .....	48,031	48,031
Computer equipment and software .....	4,052,775	3,359,761
Total property and equipment .....	13,377,679	12,160,895
Accumulated depreciation .....	(11,015,037)	(10,292,836)
	\$ 2,362,642	\$ 1,868,059
<b>Other Assets</b>		
Notes receivable, less current portion .....	\$ 852,283	\$ —
Deposits and other assets .....	64,162	107,242
	\$ 916,445	\$ 107,242
<b>Accrued expenses</b>		
Accrued payroll and related benefits .....	\$ 1,543,776	\$ 447,072
Accrued warranty costs .....	514,325	1,373,568
Other accrued expenses .....	2,057,446	2,126,471
	\$ 4,115,547	\$ 3,947,111

**TRIPATH IMAGING, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**4. Allowance for Doubtful Accounts**

A summary of the allowance for doubtful accounts activity is as follows:

	December 31,		
	2001	2000	1999
Balance, beginning of year .....	\$1,475,000	\$1,347,142	\$ 650,993
Amounts charged to expense .....	1,810,000	219,634	815,832
Amounts written off .....	(469)	(91,776)	(119,683)
Balance, end of year .....	<u>\$3,284,531</u>	<u>\$1,475,000</u>	<u>\$1,347,142</u>

**5. Acquisition of Intellectual Property**

On March 25, 1999, TriPath entered into a purchase and sale agreement to acquire the intellectual property estate of NSI, a developer of interactive, neural net technology for the computer screening of conventional Pap smears. Under the terms of the agreement, TriPath agreed to acquire the entire patent estate (including the right to pursue any claims relating to the patent estate), trademarks, regulatory applications, clinical data and all other intellectual and intangible property rights relating to the business of NSI. The purchase price consisted of cash and common stock valued at \$13,651,340. The purchase price was allocated as follows:

Patents .....	\$ 9,390,000
In-process research and development .....	2,922,000
Core technology .....	1,339,340
	<u>\$13,651,340</u>

The Company charged to expense at the date of acquisition \$2,922,000 relating to the portion of the purchase price allocated to those in-process research and development projects where technological feasibility had not yet been established. In connection with the merger, the Company wrote off \$1,339,340 relating to the core technology (Note 9).

**6. Long-Term Obligations and Commitments**

*Subordinated Term Loan*

On February 8, 2000, the Company entered into a \$7.0 million subordinated term loan with a syndicate of lenders to finance operations. The Company drew \$5.3 million of this facility in February 2000 and the balance of \$1.7 million in March 2000. As of December 31, 2001 and December 31, 2000, respectively, the balance outstanding was \$3.6 million and \$6.4 million, including a current portion of \$2.8 million at each year-end and a long-term portion of \$758,000 and \$3.6 million, respectively. The loan, which is secured by substantially all of the Company's assets, including intellectual property, accrues interest at the three-year U.S. Treasury note rate plus 8%. Accrued interest was due monthly for the first six months of each draw, at which time the outstanding principal balance became payable over thirty-month terms. In connection with this term loan, the Company issued to the lenders warrants to purchase 223,253 shares of the Company's common stock. Using a Black-Scholes pricing model, the warrants were valued upon issuance at \$675,000, which represented non-cash debt issuance costs. These warrants, which expire in 2007, were recorded as additional paid-in capital, and the resulting debt issuance costs are being amortized on a straight-line basis to interest expense over the three-year term of the loan. These warrants have a weighted-average exercise price of \$4.70 and were exercisable upon issuance.

**TRIPATH IMAGING, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

*Note Payable to Finance Company*

In December 1998, the Company entered into an agreement with an equipment financing company to provide the Company with a \$5.0 million line of credit to finance certain of the Company's equipment purchases. The Company had outstanding borrowings of \$467,400 and \$851,100 under the agreement at December 31, 2001 and 2000, respectively. The agreement has a loan term of 48 months, and the loan is secured by a security interest in the financed equipment. Interest is calculated based on the four-year Treasury Bill Weekly Average rate plus 6.121%.

*Working Capital Facility*

In February 2001, the Company renewed a \$5.0 million working capital facility with a bank. The outstanding balance is limited to an amount equal to 80% of eligible accounts receivable. The line commitment expired on January 31, 2002 and was renewed for an additional year until January 31, 2003. The line bears interest at the bank's prime rate plus 1/2% and is collateralized by substantially all of the assets of the Company. The line of credit carries customary covenants, including the maintenance of a minimum modified quick ratio and other requirements. The Company had no outstanding borrowings under this agreement at December 31, 2001.

At December 31, 2001, maturities of the outstanding debt are as follows:

2002 .....	\$2,944,781
2003 .....	790,196
	3,734,977
Less: Unamortized debt issuance costs .....	225,000
	\$3,509,977

The fair value of the Company's long-term debt, which approximates its carrying value, is estimated using discounted cash flow analysis based on the Company's current incremental borrowing rates for similar type borrowing arrangements.

*Leases*

The Company leases its office and manufacturing facilities and certain office equipment under operating leases, with various renewal options, expiring at various times through 2007.

At December 31, 2001, future minimum lease payments under these leases are as follows:

2002 .....	\$1,422,154
2003 .....	1,439,678
2004 .....	1,439,833
2005 .....	214,673
2006 .....	24,000
Thereafter .....	16,000
	\$4,556,338

Rent expense amounted to \$1,219,969, \$1,340,812 and \$1,239,923 during 2001, 2000 and 1999, respectively.

## TRIPATH IMAGING, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### *Other Long-Term Liabilities*

The Company has recorded a long-term contingent liability of \$1.5 million, at December 31, 2001, in accordance with the provisions of FASB SFAS No. 5, "Accounting for Contingencies," on the basis that the likelihood of a future event occurring is probable and reasonably estimable. This contingency relates to the Company's obligation to pay a third party an amount based on the difference between the market price of the Company's common stock on a specified date in the future and a predetermined target price. An amount of \$1.3 million was initially accrued at December 31, 2000.

The Company entered into a series of agreements with BD on July 31, 2001, to develop and commercialize molecular diagnostics and pharmacogenomic tests for cancer as part of the ongoing strategic alliance between BD and Millennium, and has accounted for the transaction in accordance with the provisions of FASB SFAS No. 68, "Research and Development Arrangements." In connection with the transaction, the Company recorded \$6.2 million in deferred research and development ("R&D") funding, which will be amortized against such expenses over thirty months on a straight line basis. In 2001, \$1.0 million of amortization was recorded against R&D expense. Included in current and other long-term liabilities are the unamortized balances of \$2.5 million and \$2.7 million, respectively.

#### **7. Income Taxes**

At December 31, 2001, the Company had net tax loss carryforwards of approximately \$181.5 million, which begin to expire in 2003 for federal income tax purposes. The Company also has approximately \$3.4 million in research and development carryforwards that begin to expire in 2003. Due to the prior issuance and sale of shares of preferred stock, the prior merger and changes in ownership, the Company has incurred "ownership changes" pursuant to applicable regulations in effect under the Internal Revenue Code of 1986, as amended. The Company's use of losses incurred through the date of these ownership changes may limit the ultimate utilization of these losses. To the extent that any single-year loss is not utilized to the full amount of the limitation, such unused loss is carried over to subsequent years until the earlier of its utilization or the expiration of the relevant carryforward period.

Approximately \$5.1 million of the net deferred tax asset is attributed to the deduction for stock options, the tax effect of which will be credited to equity when recognized.

**TRIPATH IMAGING, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

Deferred income taxes reflect the net tax effects of temporary differences between the tax basis of assets and liabilities and the corresponding financial statement amounts. Significant components of the Company's deferred income tax assets (liabilities) are as follows:

	December 31,	
	2001	2000
	(In Thousands)	
Net tax loss carryforwards .....	\$63,515	\$ 69,975
Research and development credits .....	3,417	3,508
Accrued vacation .....	107	79
Accrued warranty costs .....	180	—
Allowance for doubtful accounts .....	1,150	569
Charitable contribution carryforwards .....	15	15
Deferred compensation .....	—	443
Deferred research and development .....	1,808	—
Intangible assets, net of amortization .....	1,527	983
Inventory .....	2,751	492
Other .....	713	609
Property and equipment .....	368	475
Valuation allowance .....	<u>(75,551)</u>	<u>(77,148)</u>
	<u>\$ —</u>	<u>\$ —</u>

Due to the uncertainty of the Company's ability to generate taxable income to realize its deferred tax assets, a valuation allowance has been established for financial reporting purposes equal to the amount of the net deferred tax assets. The Company's valuation allowance was \$75.6 million and \$77.1 million at December 31, 2001 and 2000, respectively.

**8. Stockholders' Equity**

*Preferred Stock*

Pursuant to the Company's amended and restated Certificate of Incorporation, the Board of Directors has the authority, without further vote or action by the stockholders, to issue up to 1,000,000 shares of Preferred Stock in one or more series and to fix the relative rights, preferences, privileges, qualifications, limitations and restrictions thereof, including dividend rights, dividend rates, conversion rights, voting rights, terms of redemption, redemption prices, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of Common Stock. At December 31, 2001 there were no shares of Preferred Stock outstanding.

*Private Equity Transaction*

On July 31, 2001, the Company completed a private placement of securities under Regulation D of the Securities Act with BD pursuant to which BD acquired 2,500,000 shares of the Company's common stock for \$10.00 per share. The Company accounted for a portion of these proceeds in accordance with the provisions of FASB SFAS No. 68, "Research and Development Arrangements" and recorded \$6.2 million thereof as deferred research and development funding, which will be amortized against such expenses over thirty months on a straight line basis. The transaction with BD provided the Company with an additional \$25.0 million in cash. In a separate agreement, the Company and Millennium entered into a research license for the Company's evaluation of certain patents in the area of colon cancer. In consideration of this agreement, the Company issued to Millennium 400,000 shares of the Company's common stock. The Company also paid \$1 million in connection with other aspects of the transaction.

**TRIPATH IMAGING, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

On November 14, 2000, the Company completed a \$43.0 million private equity transaction with a subsidiary of Hoffmann-La Roche (“Roche”) in terms of which Roche acquired 5.0 million shares of the Company’s common stock for \$8.00 per share. Additionally, Roche simultaneously acquired, for an aggregate purchase price of \$3.0 million, warrants to purchase an additional 5.0 million shares at strike prices ranging from \$10.00 to \$15.00 per share. The proceeds from the sale of these warrants were recorded as additional paid-in capital.

On February 9, 1999, the Company completed a \$14.5 million private equity transaction, issuing 2.3 million shares of common stock to investors at a price of \$6.33 per share. In connection with the financing, the Company issued to a related party five year warrants to purchase 79,030 shares of common stock at an exercise price of \$7.45 per share.

*Equity Incentive Plans*

The Company has stock option plans (the “Plans”) under which incentive and non-statutory stock options, stock appreciation rights and restricted stock may be granted to employees, directors or consultants of the Company. Generally, options and restricted stock grants vest ratably over a 48-month term. Stock options expire ten years from the date of grant.

A summary of activity under the Plans is as follows:

	Options Outstanding	
	Number of Shares	Weighted-Average Exercise Price
Outstanding at December 31, 1999 .....	3,156,477	\$7.11
Options granted .....	1,350,763	4.50
Options exercised .....	(863,267)	1.90
Options canceled/expired .....	(822,931)	10.93
Outstanding at December 31, 2000 .....	2,821,042	6.34
Options granted .....	1,081,700	9.13
Options exercised .....	(279,061)	3.36
Options canceled/expired .....	(136,219)	8.62
Outstanding at December 31, 2001 .....	3,487,462	\$7.26

Price Range	Options Outstanding			Options Exercisable	
	Number Outstanding At December 31, 2001	Weighted-Average Remaining Contractual Life (Years)	Weighted-Average Exercise Price	Number Exercisable At December 31, 2001	Weighted-Average Exercise Price
\$0.20-0.20	163,110	2.4	\$ 0.20	163,110	\$ 0.20
1.52-2.28	11,395	1.6	1.69	11,395	1.69
2.69-3.88	43,624	4.0	3.08	39,059	3.06
4.19-6.25	2,187,686	7.7	5.23	1,225,074	5.17
6.31-9.38	123,291	7.9	7.87	55,598	7.67
9.63-14.24	633,829	8.8	10.99	197,574	11.14
15.34-21.51	300,818	6.2	16.80	300,818	16.80
29.89-29.89	23,709	4.5	29.89	23,709	29.89
\$0.20-29.89	3,487,462	7.5	\$ 7.26	2,016,337	\$ 7.39

TRIPATH IMAGING, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

SFAS 123

The Company has adopted the disclosure-only provisions of SFAS 123. In accordance with SFAS 123, the fair value of each option grant was determined by using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Year Ended December 31,		
	2001	2000	1999
Risk-free interest rate .....	4.59%	6.37%	5.34%
Expected dividend yield .....	0.00%	0.00%	0.00%
Expected lives .....	48 months	48 months	48 months
Expected volatility .....	1.02	0.90	0.75
Weighted-average fair value of grants .....	\$ 9.13	\$ 4.51	\$ 5.87

Had compensation cost for the Company's stock options been determined based on the fair value at the date of grant consistent with the provisions of SFAS 123, the Company's pro forma net loss and net loss per share would have been as follows:

	Year Ended December 31,		
	2001	2000	1999
Net loss:			
As reported .....	\$(21,679,695)	\$(17,369,456)	\$(32,556,840)
Pro forma .....	\$(24,889,266)	\$(20,060,516)	\$(38,274,434)
Net loss per common share (basic & diluted):			
As reported .....	\$ (0.61)	\$ (0.60)	\$ (1.17)
Pro forma .....	\$ (0.70)	\$ (0.69)	\$ (1.38)

Warrants

On February 9, 1999, the Company completed a \$14.5 million private equity transaction. In connection with the financing, the Company issued to a related party five year warrants to purchase 79,030 shares of common stock at an exercise price of \$7.45 per share.

On February 8, 2000, the Company closed a \$7.0 million subordinated term loan with a syndicate of lenders to finance operations (Note 6). The Company issued warrants to the lenders to purchase 223,253 shares of common stock at a weighted-average exercise price of \$4.70 per share. The warrants were exercisable upon issuance and expire in 2007. None of these warrants had been exercised as of December 31, 2001.

On November 14, 2000, the Company completed a \$43.0 million private equity transaction with Roche in terms of which Roche acquired, for an aggregate purchase price of \$3.0 million, warrants to purchase 5.0 million shares of common stock at a weighted exercise price of \$11.50 per share. The warrants were immediately exercisable and expire in 2003. None of these warrants had been exercised by December 31, 2001.

As of December 31, 2001, there were 5,302,283 warrants outstanding with a weighted-average exercise price of \$11.15. These warrants expire at various dates through 2007.

**TRIPATH IMAGING, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

*Common Stock Reserved for Future Issuance*

At December 31, 2001, the Company has reserved authorized shares of Common Stock for future issuance as follows:

	<b>December 31, 2001</b>
Outstanding stock options .....	3,487,462
Possible future issuance under equity incentive plans .....	224,774
Possible future issuance under Employee Stock Purchase Plan .....	1,000,000
Common stock warrants .....	<u>5,302,283</u>
Total shares reserved .....	<u><u>10,014,519</u></u>

*Deferred Compensation*

The Company recorded deferred compensation for the difference between the exercise price and the deemed fair value of the Company's common stock option and restricted stock grants. The amount is being amortized over the vesting period of the individual options, generally 48 months. Amortization of deferred compensation amounted to \$89,140, \$668,268 and \$814,140 during 2001, 2000 and 1999, respectively. In 2000, the Company adjusted the deferred compensation amount by \$22,237 to reflect the cancellation, accelerated vesting and non-forfeiture of options granted to terminated employees.

**9. Transaction, Integration and Restructuring Costs**

In connection with the Merger with NeoPath on September 30, 1999, certain expenses of the transaction, costs to integrate the two organizations, and expenses associated with the restructuring of the Company's business have been accrued and recorded as an expense. The following table presents the components of the expense:

	Total Expense	Payments			Balance Remaining
		1999	2000	2001	
Cash expenses:					
Transaction and professional fees	\$2,554,314	\$1,296,694	\$1,257,620	\$ —	\$ —
Personnel separation costs .....	1,098,540	443,987	448,785	205,768	—
Other costs .....	<u>553,000</u>	<u>428,822</u>	<u>124,178</u>	—	—
	<u>4,205,854</u>	<u>\$2,169,503</u>	<u>\$1,830,583</u>	<u>\$205,768</u>	<u>\$ —</u>
Non-cash expenses:					
Write-off of assets .....	<u>4,239,489</u>				
Total expenses .....	<u><u>\$8,445,343</u></u>				

Transaction costs are comprised of amounts owed to investment bankers and advisors for services rendered in conjunction with the Merger. Personnel separation costs reflect severance payments to be made to employees terminated as a result of the Merger. The non-cash write-off of assets primarily relates to property and equipment and the core technology acquired from NSI deemed to have become redundant or obsolete as a result of the Merger. Other costs include integration costs directly related to the Merger and other costs resulting from actions taken to merge the operations.

TRIPATH IMAGING, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

10. Operations by Industry Segment and Geographic Area

*Description of Products and Services by Segment*

TriPath currently operates in two business segments: Commercial Operations and Tripath Oncology (see Note 1).

*Measurement of Segment Profit or Loss and Segment Assets*

The Company evaluates performance and allocates resources based on operating profit or loss. The accounting policies of the reportable segments are the same as those described under the summary of significant accounting policies (see note 2 above). Inter-segment transfers are recorded at cost.

*Factors Management Used to Identify the Company's Reportable Segments*

The Company's reportable segments are business units that offer different products and services. The reportable segments are each managed separately because they develop and commercialize distinct products. The segments operate as separate entities.

*Results by Segment*

Results for the 1999 and 2000 financial years as reflected in the Consolidated Statements of Operations relate to the Commercial Operations segment only. The results, by segment, for 2001 follow:

	Commercial Operations Full year	2001 Tripath Oncology July to December	Total
Revenues .....	\$ 27,017,066	\$ —	\$ 27,017,066
Cost of revenues .....	12,946,717	—	12,946,717
Gross profit .....	14,070,349	—	14,070,349
Operating expenses:			
Research and development .....	6,250,441	407,722	6,658,163
Regulatory .....	1,875,683	—	1,875,683
Sales and marketing .....	18,113,324	220,036	18,333,360
General and administrative .....	9,214,766	672,626	9,887,392
	35,454,21	1,300,384	36,754,598
Operating loss .....	<u>\$(21,383,865)</u>	<u>\$(1,300,384)</u>	<u>\$(22,684,249)</u>

All revenues were from external customers. There were no inter-segment revenues. Sales to external customers of the Commercial Operations segment includes the following for the year ended December 31, 2001:

	(In thousands)
Instruments .....	\$10,236
Reagents .....	13,613
Other .....	3,168
Total revenues .....	<u>\$27,017</u>

Only the Commercial Operations segment had depreciation and amortization expense for the 2001 financial year, which amounted to \$3.9 million. The Tripath Oncology segment received \$6.2 million in deferred R&D funding from BD, which is being amortized against such expenses over thirty months on a straight-line basis. In 2001, \$1.0 million of amortization was recorded against R&D expense. The Tripath

**TRIPATH IMAGING, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

Oncology segment had total assets of \$4.1 million as of December 31, 2001 and the Commercial Operations segment total assets of \$92.6 million.

*Geographic Area Data*

Through September 30, 2000, Commercial Operation's domestic revenues were generated primarily through the Company's direct sales activities. In October 2000, the Company commenced with the planned expansion of its field sales forces, which included the contracting of an outside sales organization. International revenues continue to be derived primarily through distributors. International revenues accounted for 23%, 32% and 29% of total revenues during 2001, 2000 and 1999, respectively. The Company's largest customer accounted for 11% of total revenue in 2001 and 20% of total revenue in 2000. In 1999 the Company's four largest customers accounted for 50% of total revenues.

**11. Related Party Transactions**

The Company has a temporary arrangement with BD, a shareholder of the Company, for leasing a portion of BD's facility in Research Triangle Park, North Carolina ("RTP"). Total rent paid to BD amounted to \$5,087 during 2001. This arrangement will end during 2002 after TriPath Oncology space in the RTP area is completed sometime in mid-2002.

Included in Notes Receivable is a loan of \$25,000 made to an Officer of the Company.

**12. Employee Benefits**

The Company maintains qualified 401(k) Retirement Plans covering substantially all employees that provide for voluntary salary deferral contributions. Total expense for the plans, including employer contributions, amounted to \$263,134, \$248,671 and \$108,897 during 2001, 2000 and 1999, respectively.

The Company, beginning January 1, 2002, first offered to employees a qualified Employee Stock Purchase Plan covering substantially all employees that provide for voluntary salary deferral contributions for the purchase of Company stock subject to the provisions of the Plan. There was no expense associated with this plan recorded in 2001.

**13. Contingencies**

In the ordinary course of business, the Company is the subject of, or party to, various pending or threatened claims and litigation. In the opinion of management, settlement of such claims and litigation will not have a material effect on the Company's operations or financial position.

**14. Quarterly Results of Operations (Unaudited)**

<u>2001</u>	<u>March 31</u>	<u>June 30</u>	<u>September 30</u>	<u>December 31</u>
Revenues .....	\$ 9,287,343	\$ 6,152,580	\$ 5,250,448	\$ 6,326,695
Gross profit .....	4,734,114	3,016,334	3,045,405	3,274,496
Net loss .....	(3,203,249)	(4,160,233)	(7,493,881)	(6,822,332)
Net loss per common share (basic & diluted) ....	\$ (0.09)	\$ (0.12)	\$ (0.21)	\$ (0.18)
 <u>2000</u>	 <u>March 31</u>	 <u>June 30</u>	 <u>September 30</u>	 <u>December 31</u>
Revenues .....	\$ 7,446,816	\$ 8,100,608	\$ 8,092,645	\$ 9,011,680
Gross profit .....	3,734,089	3,872,455	4,437,468	4,601,489
Net loss .....	(2,765,114)	(5,085,310)	(2,865,950)	(6,653,082)
Net loss per common share (basic & diluted) ....	\$ (0.10)	\$ (0.18)	\$ (0.10)	\$ (0.21)

**TRIPATH IMAGING, INC.****FACTORS AFFECTING FUTURE OPERATING RESULTS**

April 2002

From time to time, TriPath Imaging, through its management, may make forward-looking public statements, such as statements concerning then expected future revenues or earnings or concerning projected plans, performance, product development and commercialization as well as other estimates relating to future operations. Forward-looking statements may be in reports filed under the Securities Exchange Act of 1934, as amended, in press releases or in oral statements made with the approval of an authorized executive officer. The words or phrases "will likely result," "are expected to," "will continue," "is anticipated," "estimate," "project" or similar expressions are intended to identify "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934 and Section 27A of the Securities Act of 1933, as enacted by the Private Securities Litigation Reform Act of 1995.

We caution you not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. In addition, we advise you that the factors listed below, as well as other factors we have not currently identified, could affect our financial or other performance and could cause our actual results for future periods to differ materially from any opinions or statements expressed with respect to future periods or events in any forward-looking statement.

We will not undertake and specifically decline any obligation to publicly release revisions to these forward-looking statements to reflect either circumstances after the date of the statements or the occurrence of events which may cause us to re-evaluate our forward-looking statements, except as required by law.

In connection with the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, we are hereby filing cautionary statements identifying important factors that could cause our actual results to differ materially from those projected in forward-looking statements made by us or on our behalf.

**RISKS RELATED TO OUR BUSINESS**

**Our oncology products are at an early stage of development and we cannot assure the commercial success of these products.**

Our oncology products are in the early stages of development and significant additional research, and development, financial resources and personnel will be required to develop them into commercially viable products and obtain regulatory approvals. We are developing and commercializing molecular diagnostic and pharmacogenomic tests for a variety of cancers through our collaboration with Becton, Dickinson and Company, or BD, as part of the ongoing strategic alliance between BD and Millennium Pharmaceuticals, Inc. Our collaboration with BD has not yet produced a viable product. We may fail to successfully develop and commercialize our oncology products if:

- pre-clinical research shows our products to be ineffective;
- they do not receive necessary regulatory approvals or otherwise meet regulatory requirements; and
- are less effective than current or alternative oncology diagnostic methods.

If we fail to develop and commercialize our oncology products, our revenues could be adversely affected.

**Our oncology products business will be negatively affected if BD or Millennium fails to deliver required certain test markers under our collaborative arrangement, or if BD fails to support, or terminates its collaboration with us.**

We conduct all of our oncology-related discovery and development activities through our collaboration with BD. TriPath Oncology is developing and commercializing molecular diagnostics and pharmacogenomic tests for cancer as part of the ongoing strategic alliance of BD and Millennium. The success of our oncology products business depends, in large part, on the fulfillment of the contractual obligations by BD and Millennium, including the delivery of validated genomic and proteomic markers discovered by Millennium under its arrangement with BD. Both BD and Millennium have significant discretion in determining the efforts and resources that they will apply to the collaboration. Our collaboration with BD may not be scientifically or commercially successful. The risks that we face in connection with this collaboration include:

- Millennium may fail to deliver validated markers under its strategic partnership with BD, which TriPath Oncology needs to develop diagnostic oncology products;
- if the collaboration between BD or Millennium is terminated, we may lose rights to certain intellectual property necessary to develop our oncology products; and
- BD or Millennium may choose to develop and commercialize, either alone or with others, products and services that are similar to or competitive with the non-exclusive or co-exclusive products and services that are the subject of the collaboration with us.

If BD or Millennium fail to fulfill their obligations under our collaborative arrangement or if BD terminates the collaboration with us, the future of our oncology products business would be adversely affected.

**Our products are subject to regulatory review, approval and regulation and we may be unable to commercialize any of our products currently in development.**

The FDA and foreign regulatory agencies extensively regulate the manufacture and sale of medical diagnostic devices for commercial use. We must comply with applicable FDA regulations, including obtaining FDA approval of products before we can market and sell them for their principal intended uses in the United States.

To obtain FDA approval for our products, we must submit a premarket approval application to the FDA. This process can be expensive and time-consuming and can take several years. Several factors may affect our ability to successfully obtain FDA approval for the commercialization of our products, including the following:

- failure of the product in preclinical studies;
- insufficient clinical trial data to support the safety or effectiveness of the product; or
- unanticipated delays or significant unanticipated costs in our efforts to secure FDA approval.

If we fail to obtain and maintain FDA approval for any of our future products, if FDA approval is delayed, or if we receive FDA approval for our products but labeling restrictions make the use of the products uneconomical to our customers, our future product sales will be far less than we anticipate and may be insufficient to sustain our operations. We have no assurance that the FDA will ever approve our future products for their principal intended use. In addition to the premarket approval application process, we may face further difficulties in connection with FDA approval of our products for the following reasons:

- FDA regulations require submission and approval of a premarket approval application supplement for certain changes to a product if the changes affect the safety and effectiveness of the product;
- even if we obtain FDA approval of our premarket approval applications, that approval may still not allow us to make some of the specific claims for which we sought FDA approval; and
- any FDA approval may include significant limitations on the indicated uses for which we may market our products, such as warnings, precautions or contraindications, requests for post-market studies, or additional regulatory requirements.

The FDA may not approve our future products or commercial enhancements to our existing products on a timely basis, if at all. Our regulatory applications also may be delayed or rejected based on changes in regulatory policies or regulations.

**Government regulation imposes significant restrictions and costs on the development and commercialization of our products.**

Any products approved by the FDA are still subject to continual government review and regulation, so long as the product is being marketed. Of our principal products, PrepStain, FocalPoint and the use of PrepStain with FocalPoint, have received FDA approval. Although we have received FDA approvals, we are still subject to continual FDA review and regulation regarding the ongoing marketing, sale and use of our cervical screening products. During this continual review process, any subsequent discovery of previously unknown or unrecognized problems with the product or a failure of the product to comply with any applicable regulatory requirements can result in, among other things:

- fines or other civil penalties;
- the refusal of the FDA to approve further premarket approval applications;
- suspension or withdrawal of our FDA approvals;
- product recalls;
- operating restrictions, including total or partial suspension of production, distribution, sales and marketing of our products;
- injunctions; or
- product seizures and criminal prosecution of us, our officers or our employees.

If we fail to maintain FDA approval for the use of our FocalPoint product with PrepStain, we will be unable to sell this joint product and our overall future sales will be far less than we anticipate and may be insufficient to sustain our operations.

**We depend on a limited number of products and these products may never gain market acceptance.**

Sales and rentals of PrepStain and FocalPoint for cervical cancer screening currently account for the substantial majority of our revenues. Market acceptance of PrepStain and FocalPoint, as well as their combined use, will depend on our ability to convince clinical laboratories, physicians, third party payors and other health care providers and consumers that our products can address the limitations of the conventional Pap smear process. We may not be able to successfully establish that our products are better and more cost competitive compared to the conventional Pap smear process. In addition, the market may not accept our cervical cancer products as a replacement to the conventional Pap smear collection process. Even if PrepStain, FocalPoint, and the utilization of PrepStain with FocalPoint and other products do gain market acceptance, their level of sales will still largely depend on the availability and level of reimbursement from third-party payors, such as private insurance plans, managed care organizations and Medicare and Medicaid. There can be no assurance that we will achieve market acceptance for PrepStain, FocalPoint, or their combined use, and the failure to do so would have a material adverse effect on our business, financial condition and results of operations.

In addition, the market may not accept any of the oncology products that we develop. While various diagnostic and pharmacological oncology tests are currently available, few tests offer an integrated solution for diagnosing cancer at the earliest possible stage, providing individualized predictive and prognostic information, guiding treatment selection for patients with cancer, and predicting disease recurrence. Market demand for

our oncology products will depend primarily on acceptance by clinical laboratories, physicians and third party payers. Commercial acceptance of our oncology tests will depend upon several factors, including:

- their potential advantage, including their cost-effectiveness over alternative diagnostic methods;
- our ability to compete with similar or superior products developed by our competitors;
- our ability to build and maintain, or access through third parties, a capable sales force; and
- qualification of our products for third party medical insurance coverage and reimbursement.

If our oncology products do not achieve significant market acceptance, our revenues could be adversely affected.

**We have a history of operating losses and an accumulated deficit and we may never become profitable.**

We have a history of operating losses and we expect losses to continue for the next several years as we continue to market our products, develop new products and perform additional clinical studies. As of December 31, 2001, we had cumulative net losses of approximately \$206.4 million. While our products have grown in acceptance as measured by our revenues, we still operate in a very competitive environment. These losses resulted principally from the costs of our research and development activities and expenses in excess of revenues. Our operating expenses have been concentrated in the following areas:

- research and development activities;
- sales and marketing activities, including the cost and effect of promotional discounts, sales, and marketing programs and strategies; and
- regulatory issues, including activities in connection with premarket approval applications to the FDA;

We expect marketing and sales expenses associated with our products to either continue at the rate of 2001 or increase in the future, which could contribute to financial losses for us. These expenses are a result of our expanded marketing and sales efforts to continue the commercial rollout of our products. Our profitability is subject to uncertainty and will depend on a number of factors including:

- receipt of regulatory approvals for future products in a timely manner;
- successful marketing of our products in the United States;
- the extent to which our products gain market acceptance;
- ability to manufacture our products at an acceptable cost and with acceptable quality;
- introduction of alternative technologies by our competitors;
- the timing and volume of system placements;
- availability of reimbursement from third-party payors, and the extent of coverage; and
- ability to establish internal financial controls and other infrastructure necessary to support large-scale commercial operations.

We expect to continue incurring overall net operating losses until product sales and service revenues sufficiently fund our operations and while our oncology business is developing products that can be commercially introduced into the market. We cannot be certain that we will ever become profitable.

**We cannot be certain of our future capital needs and additional financing may not be available when we need it.**

Since beginning operations in November 1996, we have financed our operations through the private placement and public sales of equity securities, debt facilities and limited product sales. We have had negative cash flow from operations since inception, and we expect negative cash flow from operations to continue at least through the next 12 to 24 months. At December 31, 2001, we had approximately \$56.0 million in cash,

cash equivalents and short-term investments. We believe that our existing cash and existing debt and lease financing will be sufficient to enable us to meet our future cash obligations through, at least, 2002.

We may be unable to obtain adequate funds, either through financial markets or from collaborative or other arrangements with corporate partners or other sources, when we need them, or we may be unable to find adequate funding on favorable terms, if at all. If we are unable to fund our future capital requirements, it would significantly limit our ability to continue our operations.

The extent of our future capital requirements depends on several factors, including:

- the timing of achieving profitability;
- the timing and costs of product introductions;
- the extent of our ongoing research and development programs, including that at TriPath Oncology;
- the progress and scope of clinical trials;
- the timing and costs required to receive both United States and foreign governmental approvals for new products in development;
- the extent to which our products gain market acceptance;
- demand for and sales of our combined PrepStain and FocalPoint systems for cervical cancer screening and of FocalPoint GS in the United States, if and when it gains FDA approval;
- the resources required to further develop our marketing and sales capabilities domestically and internationally, and the success of those efforts;
- the resources required to expand manufacturing capacity;
- the costs of training laboratory personnel to become proficient with the use of our products; and
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;

Many of these factors may be out of our control. There is no guarantee that the assumptions underlying our estimates about our needs for future capital will prove to be accurate.

**Our future financing arrangements may impact the value of your investment or may impact our rights to our intellectual property.**

We may choose to raise additional funding to meet our future capital requirements through a variety of financing methods, including lease arrangements, debt or equity financings, or strategic alliances. If we were to raise additional funding through the sale of equity or securities convertible into equity, your proportionate ownership in TriPath Imaging may be diluted. In addition, if we obtain additional funds through arrangements with collaborative partners, we may have to relinquish rights to certain of our technologies or potential products that we would otherwise seek to develop or commercialize ourselves. Additional funding may not be available when needed or on terms acceptable to us, which would have a material adverse effect on our liquidity and capital resources, business, financial condition and results of operations.

**If our strategic partnerships are unsuccessful, our earnings growth will be limited.**

An important element of our strategy is to enter into strategic partnerships for the research and development of alternative applications for our extensive body of intellectual property. We currently have a strategic arrangement with BD for the development of diagnostic and pharmacogenomic oncology tests and we may enter into additional partnerships in the future. We believe that recent advances in genomics, biology, and informatics are providing new opportunities to leverage our proprietary technology. The success of these arrangements is largely dependent on technology and other intellectual property contributed by our partners, as well as their efforts, resources and skills. Our existing and future strategic partnerships are also dependent upon our partners' continued willingness to collaborate with us, as opposed to our competitors. There can be

no assurance that we will succeed in implementing and finalizing any new strategic partnerships to facilitate the exploitation of our intellectual property estate. The failure to do so could have a material adverse effect on our future prospects inside and outside of the cervical cytology or diagnostic oncology markets and could impact our financial condition and results of operations.

**We have limited manufacturing experience and capacity and we may not be able to establish sufficient manufacturing capability and capacity, either of which could have a material adverse effect on our business.**

We manufacture PrepStain and FocalPoint, and related products either at our Burlington, North Carolina, or at our Redmond, Washington facilities. Currently, we have limited manufacturing experience and capabilities for high volume test kit manufacturing. While we believe we have sufficient capacity to meet near term customer demand for our cervical cytology products, we may have to substantially increase our manufacturing capabilities in the future if our products gain wider market acceptance. We may not be able to recruit and retain skilled manufacturing personnel to establish sufficient manufacturing capability and capacity. Even if we are able to establish sufficient manufacturing capability and capacity, we still may be unable to manufacture our products:

- in a timely manner;
- at a cost or in quantities necessary to make them commercially viable;
- in conformance with quality system requirements; or
- in a manner which otherwise insures our products' quality.

If we cannot successfully increase our manufacturing capability and capacity, or successfully contract with third parties to manufacture our products, our profitability will suffer.

**We may not be able to manufacture our products in a timely or cost effective manner because we depend on single and limited source suppliers for our products' components.**

We currently obtain certain components for our products on a single source basis from certain suppliers. If any of these sole-source suppliers are unable to provide an adequate and constant supply of components, we will need to modify any components provided by additional or replacement suppliers. If we are unable to establish additional or replacement sources of supply on a cost-competitive and timely basis from these suppliers, we may need to delay or halt our manufacturing process. If any of the components of our products were no longer available in the marketplace, we could be forced to further develop our technology to incorporate alternate components. We also may try to establish relationships with additional suppliers or vendors for components for our products, so long as we are not prohibited from doing so by any existing contractual obligations. We may not be able to further develop our technology to incorporate new components or establish relationships with additional suppliers or vendors for the necessary components of our products.

In addition, use of any new components or replacement components from alternative suppliers into our products may require us to submit PMA supplements to the FDA. We would then need FDA approval on any PMA supplements we have filed before we could market our products with new or replacement components. Ultimately, we may not be able to successfully develop, obtain, or incorporate replacement components into our products. Even if we were able to successfully incorporate new components into our products, the FDA may not approve these new components quickly, if at all.

**We have limited marketing and sales resources which could hurt our ability to become profitable.**

During the last quarter of 2000 and throughout 2001, we have added to our marketing and sales forces to more effectively market our products. Even with the increased size of our sales force, we may not be able to successfully promote our products to clinical laboratories, health care providers, including physicians, and third-party payors. In addition, we must educate health care providers and third-party payors regarding the clinical benefits and cost-effectiveness of our products because of the market's limited awareness. We may not

be able to recruit and retain additional skilled marketing, sales, service or support personnel to help in our achievement these goals when needed.

Our marketing success in the United States and abroad will depend on whether we can:

- obtain required regulatory approvals;
- successfully demonstrate the cost-effectiveness and clinical-effectiveness of our products;
- further develop our direct sales capabilities; and
- establish arrangements with contract sales organizations, distributors and marketing partners.

If we cannot successfully expand our marketing and sales capabilities in the United States and in international markets, we may never become profitable.

**We may have difficulty managing the expansion of our operations, and failure to do so will harm our business.**

We are experiencing growth in our employee base and in the scope of our operations, and we anticipate that further expansion will be required to achieve growth in our customer base and to develop and seize market opportunities. This expansion could place a significant strain on our senior management team and on our operational and financial resources.

To manage the expected growth of our operations and personnel, we will need to improve existing, and implement new operational and financial systems, procedures, and controls. We also will need to expand, train, and manage our growing employee base as well as expand and maintain close coordination among our sales and marketing, finance, administrative, and operations staff. Further, we may be required to enter into additional relationships with various suppliers and other third parties necessary to our business. A successful continued expansion may also require us to further develop expertise in complex joint venture negotiations. We cannot guarantee that our current and planned systems, procedures, and controls will be adequate to support our future operations, that we will be able to hire, train, retain, motivate, and manage the required personnel or that we will be able to identify, manage, and benefit from existing and potential strategic relationships and market opportunities. If we do not effectively manage the budgeting, forecasting, and other process-control issues presented by such expansion, our business will suffer. If we are unable to undertake new business due to a shortage of staff or resources, our growth will be impeded. Therefore, there may be times when our opportunities for revenue growth may be limited by the capacity of our internal and external resources rather than by the absence of market demand.

In 2001, we made some significant changes to our management team. Although we believe that the new members of our management team are currently integrated with the other members of our management team, we cannot assure you that our management team will be able to continue to work together effectively or manage our growth successfully. We believe that the successful integration of our management team is critical to our ability to manage its our operations effectively and support our anticipated future growth.

**We depend on patents, copyrights, licenses and other proprietary rights to grow our business and we may not be able to adequately protect all of our proprietary rights.**

Our long-term success largely depends on our ability to market products that are technologically competitive. If we fail to obtain or maintain these protections, we may not be able to prevent third parties from using our proprietary rights. To protect our proprietary technology, rights and know-how, we rely on a combination of patents, trade secrets, copyrights; and confidentiality agreements.

We currently hold over 100 over foreign patents, over 110 over U.S. patents and have six additional U.S. patents pending. These patents will expire from 2003 through 2019. Our reliance on patents poses the following risks:

- our pending patent applications may not ultimately issue as patents;
- patents we obtain may not be broad enough to protect our proprietary rights;
- the claims allowed in any of our existing or future patents may not provide competitive advantages for our products;
- competitors may challenge or circumvent our patents or pending applications; and
- in certain foreign countries, protection of our patent and other intellectual property may be unavailable or very limited.

This may make the possibility of piracy of our technology and products more likely. We cannot guarantee that the steps we have taken to protect our intellectual property will be adequate to prevent infringement or misappropriation of our technology. In addition, detection of infringement or misappropriation is difficult. Even if we do detect infringement or misappropriation of our technology, we may be unable to enforce our proprietary rights, which could result in harm to our business. We may engage in litigation to attempt to:

- enforce our patents;
- protect our trade secrets or know-how;
- defend ourselves against claims that we infringe the rights of others; or
- determine the scope and validity of the patents or intellectual property rights of others.

Any litigation could be unsuccessful, result in substantial cost to us, and divert our management's attention, which could harm our business.

**The risk of third-party claims of infringement against us is high because our industry depends on patents and other proprietary rights.**

The large role that patents play in our industry in general may pose the following risks for us:

- we cannot be sure that our products or technologies do not infringe patents of competitors that may be granted in the future pursuant to pending patent applications;
- we cannot be sure that our products do not infringe any existing patents or proprietary rights of third parties; and
- we cannot be sure that a court would rule that our products do not infringe any existing third-party patents or that a court would invalidate any existing patents in our favor.

If a court were to uphold any claims of infringement made by existing patent holders against us, we could then be:

- prevented from selling our products;
- required to pay damages;
- required to obtain licenses from the owners of the patents; or
- required to redesign our products.

In the event that a court was to uphold a claim of patent infringement against us, we may not be able to obtain licenses from the owners of the patents or be able to successfully redesign our products to avoid patent infringement. If we were unable to obtain the necessary licenses or successfully redesign our products, it could seriously harm our ability to become a profitable company.

The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial. Such litigation may also cause a diversion of our management's time and attention from our business. Some of our competitors may be able to sustain the financial and other costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to continue our operations.

**We face special risks related to international sales and operations because we have limited experience in conducting our business in other countries.**

We are currently selling our products to customers in Australia, Asia, Canada, Europe, and South America. While we are evaluating marketing and sales channels abroad, including contract sales organizations, distributors and marketing partners, we have very limited foreign sales channels in place. There can be no assurance that we will successfully develop significant international sales capabilities or that, if we establish such capabilities, we will be successful in obtaining reimbursement or any regulatory approvals required in foreign countries. Our international sales and operations may be limited or disrupted by the imposition of government controls, export license requirements, political instability, trade restrictions, changes in tariffs, difficulties in staffing and managing international operations, changes in applicable laws, less favorable intellectual property laws, longer payment cycles, difficulties in collecting accounts receivable, fluctuations in currency exchange rates and potential adverse tax consequences. Foreign regulatory agencies often establish product standards different from those in the United States and any inability to obtain foreign regulatory approvals on a timely basis, if at all, could have a material adverse effect on our international business operations. Additionally, if significant international sales occur, our business, financial condition and results of operations could be adversely affected by fluctuations in currency exchange rates as well as increases in duty rates. There can be no assurance that we will be able to successfully commercialize our products or any future products in any foreign market.

**Our stock price is highly volatile and the value of your investment will likely fluctuate.**

Our stock price has, from time to time, experienced extreme price and volume fluctuations. Often these fluctuations are unrelated or disproportionate to our actual operating performance. Many factors could cause the market price of our stock to decline, including:

- failure to successfully implement aspects of our growth strategy;
- failure to achieve revenue and profitability results expected among those in the investment community;
- failure to meet research and development goals related to our products and services;
- technological innovations by our competitors or introductions of competing technologies;
- investor perception of the biotechnology and medical device industry; and
- general technology or biotechnology trends.

Occasionally, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought such a lawsuit against us, even if the lawsuit was without merit, we could incur substantial costs defending the lawsuit. The lawsuit would also divert the time and attention of our management from our business.

**Our controlling stockholders have the ability to influence significant decisions regarding our future.**

Roche is our single largest stockholder. As of March 25, 2002, Roche beneficially owned approximately 21% of our outstanding common stock. Roche also has the right to purchase 5,000,000 additional shares of our common stock through the exercise of warrants and has certain anti-dilution rights with respect to these warrants in order maintain its existing level of ownership. Roche also has the right to designate one member of our Board of Directors.

As of March 25, 2002, BD beneficially owned approximately 7% of our outstanding common stock. As a result, our controlling stockholders are able to significantly influence all matters requiring stockholder approval, including the election of directors and the approval of significant corporate transactions. This concentration of ownership could also delay or prevent a change in control of us that may be favored by other stockholders.

## **RISKS RELATED TO OUR INDUSTRY**

### **We may be unable to attain or maintain the required compliance with regulations governing manufacturing of medical diagnostic devices.**

Manufacturers of medical diagnostic devices face strict federal regulations regarding the quality of manufacturing. For example, the FDA periodically inspects the manufacturing facilities of diagnostic device manufacturers to determine compliance with regulations. Our current and future manufacturing and design operations must comply with these and all other applicable regulations, including regulations imposed by other governments. If we fail to comply with quality systems regulations we could face civil or criminal penalties or enforcement proceedings. These proceedings may require us to recall a product, to stop placing our products in service or to stop selling our products. Similar results could occur if we violate equivalent foreign regulations. We may not be able to attain or maintain compliance with quality systems requirements. Any failure to comply with the applicable manufacturing regulations would have a material adverse effect on our business.

### **If we are unable to keep up with technological change, our products or services may become obsolete.**

Competition in the medical device industry is intense. The diagnostic market for cervical cancer currently consists of both the conventional Pap smear procedure and new and developing technologies. Some of these newly-developed technologies have already received FDA approval with product labeling that has been marketed as more effective than the conventional Pap smear for the detection of disease in certain patient populations. Within the diagnostic market for cervical cancer, we face direct competition from companies that manufacture thin-layer slide preparation or automated screening systems. Our products could be rendered obsolete or uneconomical because of:

- technological advances by current or future competitors;
- the introduction and market acceptance of competitors' products; or
- the introduction and market acceptance of new cervical cancer detection methods.

We may not be able to successfully compete against companies marketing products based on competing technologies. Certain of our existing and potential competitors may have several competitive advantages over us because they:

- possess greater financial, marketing, sales, distribution and technological resources;
- have more experience in research and development, clinical trials, regulatory matters, customer support, manufacturing and marketing;
- have received third-party payor reimbursement for their products; or
- they may collaborate or merge with other competitors in our industry and leverage their combined intellectual property and resources against us.

These competitors may manufacture, market and sell their products or services more successfully than us, which could adversely affect our product sales.

In February 2002, one of our main competitors, Cytoc Corporation, announced its intention to merge with Digene Corporation, one of our collaborators with whom we are working to develop HPV tests. The proposed transaction is subject to review by the Federal Trade Commission under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. The Federal Trade Commission has extended its investigation beyond the initial

30-day waiting period and has requested additional information from Cytoc pertaining to the proposed merger. There can be no assurance that the Federal Trade Commission will not permit the proposed merger to take place. The successful completion of the Cytoc-Digene merger could prevent us from incorporating HPV testing into our existing products which could have a material adverse effect on our business.

Our products must remain competitive in accuracy and effectiveness, cost, including both charges by us to the laboratory and the laboratory's labor and overhead costs, convenience, perception among influential opinion leaders, including cytopathologists, other physician groups, and laboratories, and processing speed and reliability. To effectively compete, we must keep pace with the product development and technological change in our industry. Our products must demonstrate accuracy and cost effectiveness that equals or exceeds conventional preparation and review of Pap smears and the technology that may be offered by our competitors. We cannot guarantee that our products will be competitive in any of these areas.

**If we fail to obtain adequate levels of third-party reimbursement for our products, the commercial success of our products will be significantly limited.**

Our ability to successfully sell our products for cervical cancer screening in the United States and other countries depends on the availability of adequate reimbursement from third-party payors such as private insurance plans, managed care organizations and Medicare and Medicaid. Virtually all of our revenues will be dependent on customers who rely on third party reimbursement. Third-party healthcare payors in the United States are increasingly sensitive to containing healthcare costs and heavily scrutinize new technology as a primary factor in increased healthcare costs. Third-party payors may influence the pricing or perceived attractiveness of our products and services by regulating the maximum amount of reimbursement they provide or by not providing any reimbursement. Medical community or third-party healthcare payors may deny or delay acceptance of our products or may provide reimbursement at levels that are inadequate to support adoption of our technologies.

If these third-party payors do not reimburse for our preparation and screening products, or only provide reimbursement significantly below the amount laboratories charge patients to perform screening with our products, our potential market and revenues will be significantly limited. Use of our products may never become widely reimbursed, and the level of reimbursement we obtain may never be sufficient to permit us to generate substantial revenue.

A significant part of our strategy is to market PrepStain and FocalPoint together. To successfully market FocalPoint and PrepStain together, a Common Procedural Terminology Code, or a CPT code, will need to be established covering the combined use of these products. The CPT Editorial Board meets infrequently to review and establish new CPT codes. Any delay in having a CPT code established for the use of FocalPoint with PrepStain, if a CPT code is established at all, could hamper the marketing of the combined product and have a material effect on our business.

Convincing third-party payors to provide reimbursement is a costly and time consuming process because reimbursement approval is required from each payor individually; and obtaining this approval from the third-party payor typically requires the presentation of scientific and clinical data to support the use of the products. Whether a third-party payor is willing to provide reimbursement for the use of our products at a level that can allow our company to succeed depends on several unpredictable factors, including:

- the level of demand for our products by physicians;
- the payor's determination that our products are an improvement over the conventional Pap smear process; and
- the payor's determination that our products are safe and effective, medically necessary, appropriate for specific patient populations, and cost effective.

We may face particular difficulties convincing third-party payors that our products are cost effective because the up-front, direct costs of using the products will initially be greater than the cost of the

conventional Pap smear. As a result, we will need to convince third-party payors that the use of our products will result in a net overall cost savings to the health care system.

**We can only sell our products to a limited number of customers.**

A significant portion of our product sales will be concentrated among a relatively small number of large, and medium-sized, clinical laboratories. Moreover, due to consolidation in the clinical laboratory industry, we expect that the number of potential domestic customers for our products may decrease. These factors increase our dependence on sales to the largest clinical laboratories and the bargaining power of those potential customers. Our market research indicates that nearly 40% of all U.S. Pap smears are processed by the two largest laboratories. Each of these companies operates multiple laboratory facilities nationwide.

We will have to make this number of potential customers aware of our products and then convince them to accept and use our products. To gain acceptance of our products within this small customer base, we will have to successfully demonstrate the benefits of our products over the conventional Pap smear process and other alternative methods of sample collection, slide preparation and cervical cancer screening. In addition, to generate demand for our products among these clinical laboratories, we believe that we must:

- educate doctors and health care providers on, and convince them of, the clinical benefits and cost-effectiveness of our products; and
- demonstrate to doctors and health care providers that adequate levels of third-party payor reimbursement will be available for our products.

Ultimately, we may not be able to successfully sell our products to large clinical laboratories. Even if we do successfully sell our products to large clinical laboratories, those sales may not generate enough revenue to make us a profitable company.

**We are at risk of product liability claims and may not maintain adequate insurance against such liabilities.**

The commercial screening of Pap smears has historically generated significant malpractice litigation. As a result, we face product liability, errors and omissions or other claims if our products are alleged to have caused a false-negative diagnosis. Although we have product liability insurance, it could become increasingly difficult for us to obtain and maintain product liability coverage at a reasonable cost or in amounts sufficient to protect us against potential losses. If we are able to obtain adequate product liability insurance at a reasonable cost a successful product liability claim or a series of claims brought against us could require us to pay substantial amounts that would decrease our profitability, if any.

**Our success depends on our ability to retain our key personnel.**

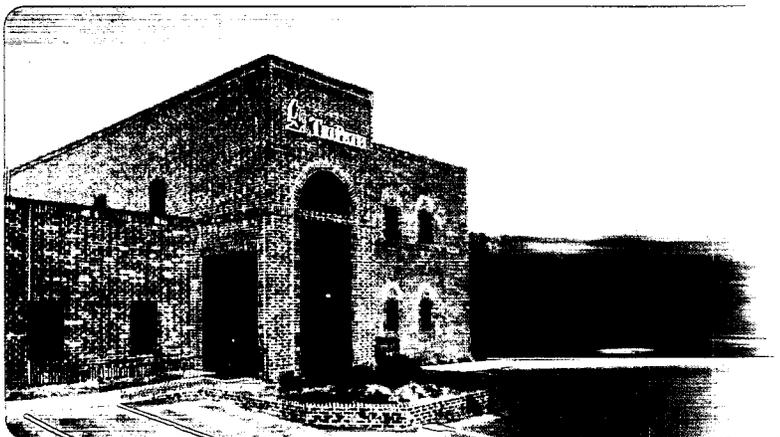
We will depend heavily on the principal members of our management and scientific staff. The loss of their services might impede achievement of our strategic objectives or research and development. Our success depends on our ability to retain key employees and to attract additional qualified employees, which may be particularly difficult to do in the future. Competition for highly skilled scientific and management personnel is intense, particularly in the geographic areas in which we currently are located, and these resources are scarce relative to the needs of a growing high technology business sector. The failure to recruit such personnel or the loss of existing personnel could adversely affect our business.



taking technology **FARTHER**

#### COMPANY PROFILE

TriPath Imaging™, Inc., headquartered in Burlington, North Carolina, develops, manufactures, markets, and sells products for cancer detection, diagnosis, staging, and treatment selection. In so doing, we are applying our proprietary technologies to develop and commercialize an array of products designed to improve the clinical management of cancer in 21 countries including the United States. We were formed in September 1999 through the merger of AutoCyte®, Inc. and NeoPath, Inc. and acquisition of the technology and intellectual property of Neuromedical Systems, Inc. We were created to leverage the complementary nature of the products, technologies, and intellectual property developed by our predecessor companies, all of whom were early pioneers in the application of computerized image processing and analysis to detect the often subtle cellular abnormalities associated with cancer and its precursors. To date, we have developed an integrated solution for cervical cancer screening and other products that deliver image management, data handling, and prognostic tools for cell diagnosis, cytopathology and histopathology. We believe that recent advances in genomics, biology, and informatics are providing new opportunities and applications for our proprietary technology.



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China  
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Germany  
Hong Kong  
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Korea  
Philippines  
Portugal  
Switzerland  
Taiwan  
The Netherlands  
United Kingdom  
United States



Front l-r: Paul R. Sohmer, Stephen P. Hall; Back l-r: John G.R. Hurrell, Ray W. Swanson

# LEADING the way

## **CORPORATE OFFICERS**

### **Paul R. Sohmer, M.D.**

President, Chief Executive Officer and  
Chairman of the Board

### **Stephen P. Hall**

Senior Vice-President and Chief Financial Officer

### **John G.R. Hurrell, Ph.D**

Senior Vice-President, TriPath Oncology

### **Ray W. Swanson**

Senior Vice-President, Commercial Operations

## **BOARD OF DIRECTORS**

### **Thomas A. Bonfiglio, M.D.**

Senior Attending Pathologist and Head, Division  
of Pathology at The Rochester General Hospital

### **Richard A. Charpie, Ph.D.**

Managing General Partner, Ampersand Ventures

### **Haywood D. Cochrane, Jr.**

President and Chief Executive Officer, Meridian  
Corporate Healthcare

### **Robert E. Curry, Ph.D.**

General Partner, Sprout Group

### **David A. Thompson**

Chief Executive Officer, Diagnostic Marketing  
Strategies; Past President, Diagnostics Division,  
Abbott Laboratories

## **CORPORATE INFORMATION**

### **Registrar and Transfer Agent**

American Stock Transfer & Trust Company, Inc.  
59 Maiden Lane  
New York, New York 10038

### **Independent Auditors**

Ernst & Young, LLP  
Raleigh, North Carolina

### **Legal Counsel**

Palmer & Dodge  
Boston, Massachusetts

### **Stock Symbol**

TriPath Imaging common stock trades on the  
Nasdaq National Market under the symbol "TPTH".

### **Annual Meeting**

The annual meeting of stockholders will be held  
on Thursday May 23, 2002 at 10:00 a.m. at the  
Country Suites, 3211 Wilson Drive, Burlington,  
North Carolina.

Our Transfer Agent is responsible for handling  
stockholder questions regarding lost stock  
certificates, address changes, and changes of  
ownership or name in which shares are held.

Copies of our Form 10-K, Forms 10-Q, our  
quarterly earnings releases, or other recent news  
releases may be obtained through our corporate  
homepage, [www.tripathimaging.com](http://www.tripathimaging.com), or by  
writing to:

Investor Relations  
TriPath Imaging, Inc.  
780 Plantation Drive  
Burlington, North Carolina 27215

# gaining MOMENTUM

>>Received FDA approval for the PrepMate™, an accessory to the PrepStain™ System, and the manual method for preparation of SurePath™ thin layer slides for cytologic screening for cancer of the uterine cervix.

>>Entered into an arrangement with Becton, Dickinson and Company, (BD) to develop molecular diagnostic and pharmacogenomic tests for malignant melanoma and cancer of the prostate, breast, ovary and cervix.

>>BD invested \$25 million in TriPath Imaging in exchange for 2.5 million newly issued shares of the Company's common stock, making BD our second largest stockholder.

>>Deployed additional sales and marketing representatives to increase our market presence in the cervical cytology market.

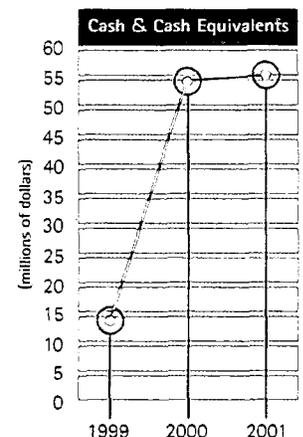
>>Received Canadian approval to market our PrepStain™ and SurePath™ products in Canada and secured multi-year agreement with MDS and DynaCare.

>>Approximately 40 papers and abstracts were presented at various scientific meetings during 2001, including 20 at the American Society of CytoPathology in November.

>>Received FDA Approval to screen PrepStain™ thin layer slide preparations on the FocalPoint™ Slide Profiler. We are the first and only company to offer laboratories a screening system that can address both thin-layer slide preparation and conventional Pap smears on a single computerized fully integrated solution for thin-layer slide preparations for cervical cancer screening. This approval sets the stage for our next generation of products.

>>Signed 10 integrated system agreements within 90 days of FDA approval for our integrated cervical cytology system.

>>In the fourth quarter of 2000, we launched the FocalPoint™ GS, the next generation of the FocalPoint™ system for use outside the United States. The FocalPoint™ GS further improves the cervical screening process by automating the microscopic analysis of SurePath™ thin-layer slides or conventional Pap smears designated for further review by the FocalPoint™ Slide Profiler.





**Paul R. Sohmer, M.D.**  
President, Chief Executive Officer and  
Chairman of the Board

## MOVING forward

### TO OUR STOCKHOLDERS

2001 was a remarkably eventful year... a year in which we took many significant and often bold steps to position the company to create value for our stockholders. It was a year in which we transitioned from a technology driven to a market driven company. It was year in which we rationalized our organization to leverage the opportunities presented by our commercially available product portfolio today and the future opportunities presented by our unique technology platforms. It was a year in which we achieved critical milestones that have created opportunities to leverage the full breadth of our value creating technology and human assets. It was a year in which we significantly increased the commercial scope of our proprietary technologies. It was a year in which we began to create exciting new opportunities for growth through the application of recent advances in genomics, biology, and informatics. It was a year in which we transformed the company.

**We transitioned from a  
technology driven to a  
market driven company”**

We are a very different company today. Look no further than our use of resources. In 2000, 56% of operating expense was spent on general administrative expenses, while only 16% was invested in marketing and sales. In 2001, 27% of operating expense was spent on general administrative expenses, while nearly 50% was invested in marketing and sales. We are a very different company.

We are now applying our proprietary technologies and know-how to create an array of products designed to improve the clinical management of cancer. Today, we develop, manufacture, market and sell products for cancer detection, diagnosis, staging, and treatment selection. We have developed and commercialized the only integrated solution for cervical cancer screening. We have developed and commercialized imaging products that deliver image management, data handling, and prognostic tools for cell diagnosis, cytopathology, and histopathology. We are now developing a new generation of molecular diagnostic and pharmacogenomic tests for malignant melanoma and cancer of the cervix, breast, ovary, colon, and prostate.

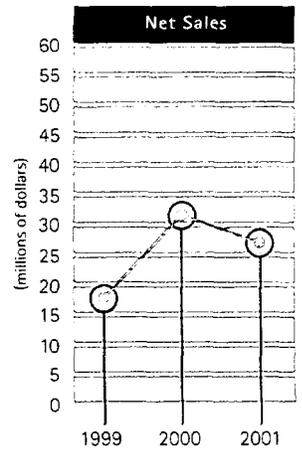
### TRIPATH CARE TECHNOLOGIES™

In late 2001, we initiated a new campaign to further communicate our corporate vision and the value created by our growing product portfolio. We adopted the trademark TriPath Care Technologies™ to communicate the broad nature of our corporate vision and to describe our product offering, including the i<sup>3</sup> Series™ and SlideWizard® product lines. We are no longer simply a "Pap Smear Company", a "specimen collection" company, an "imaging" company, or even a "molecular diagnostics" company. We are now applying our energy, technology, and know-how to fulfill unmet clinical needs rather than to expand our menu of slick technologies. The market and not the technology will drive our mission.

### ORGANIZING FOR SUCCESS: A New Management Team

To leverage the opportunities presented by our current commercial business and the compelling nature of our technology, we organized into two operating units. We have built our Commercial Operations to manage the market introduction, sales, service, manufacturing, and ongoing development of our current products, and to serve as a commercial conduit for all new products we develop in the future, including our molecular and pharmacogenomic tests for cancer. TriPath Oncology, a wholly-owned subsidiary of TriPath Imaging, was created to manage the development of molecular diagnostic and pharmacogenomic tests for cancer. Each operating unit has a unique challenge. Our Commercial Operations must drive the commercialization of current and future products. TriPath Oncology will drive the development of a new line of products that will support our growth into the future.

To lead each of these business units, we have recruited an outstanding, experienced, and professional management team. Ray Swanson, who brings years of marketing, sales, and general management experience to his position, leads our Commercial Operations team. Under his leadership, we have grown our sales and marketing team to over 110 professionals and have repositioned our current product portfolio for success in the years to come. John Hurrell, who brings years of experience in the development of novel diagnostic technologies, leads our TriPath Oncology team. Under his leadership, we have built a world-class team of scientists and marketing professionals, and have taken the initial steps to commercialize the first of our new molecular diagnostic products.



We have built a world-class team of scientists and marketing professionals”

## CHANGING THE MIX: Commercial Operations in 2001

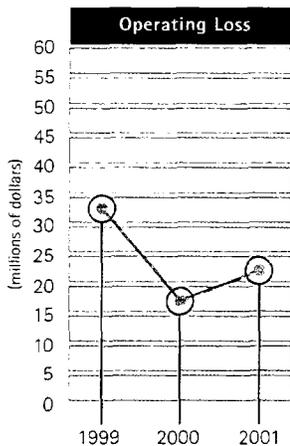
In 2001, we continued, in earnest, our efforts initiated in 2000 to transform our company from an internally focused and technology driven organization, to introduce a strong market driven approach to all of our activities, and to reposition our current product portfolio for commercial success. We successfully executed on six key initiatives:

- 1) We expanded our sales and marketing team and created a strong marketing and sales base within the organization. Today, we employ approximately 110 sales and marketing professionals who target each of our three key customer constituencies: the payor, the clinician, and the laboratory professional.
- 2) We refined our market position and enhanced brand awareness through the rebranding of our cervical screening products under the i<sup>3</sup> Series™ product line. Within the i<sup>3</sup> series line, individual products have been renamed to better communicate the value they provide to the patient, the clinician, and the laboratory professional.

Our i<sup>3</sup> series line of products includes the SurePath™ Test Pack, formerly called CytoRich®, a proprietary, liquid-based cytology sample collection, cell preservation and transport system; PrepStain™, formerly called the AutoCyte PREP System, an automated thin layer slide preparation system; and the FocalPoint™ Slide Profile System, formerly called the AutoPap® System, a slide screening system that uses proprietary technology to distinguish between normal thin-layer or conventional Pap smear slides from those that have the highest likelihood of abnormality.

Our i<sup>3</sup> Series™ product line is the only integrated system for the collection, preparation, staining and computerized analysis of conventional Pap smears and thin-layer slide preparations.

- 3) We changed our product mix and improved the resulting economics by shifting our focus from capital equipment sales and third party leasing arrangements to higher margin reagent and disposable sales and reagent rentals and in-house leasing arrangements for capital equipment. Concurrently, we directed our sales organization to target laboratories whose increased test volumes provide greater opportunity for reagent sales. While the shift from capital equipment sales and third party leasing arrangements resulted in reduced up-front revenue recognition, we believe that this will result in an increase in the average unit sales price for SurePath™ and PrepStain™ related disposables and significant upside related to the ongoing revenue stream that we would not realize with capital equipment sales.
- 4) We sought to build a "franchise" among academic centers of excellence. We continued to add high profile "opinion leaders" to our customer list.
- 5) We actively encouraged the presentation and publication of independent investigators experience with our SurePath™ and PrepStain™ products. In excess of 40 papers describing the performance of our products were published or presented at international and national meetings in 2001.
- 6) We gained FDA approval for FocalPoint™ Screening of SurePath™ thin-layer slides and the PrepMate™ accessory to our PrepStain™ System, and a Medical Device License in Canada to market both our PrepStain™ System and the PrepMate™ Accessory.



These management initiatives are reflected in the revenues generated for 2001 and, we believe will significantly impact our revenues recorded in the future. Sales from consumable reagents and disposables increased 90% from 2000. Sales related to the SurePath™ and PrepStain™ systems increased 16% and reflect revenues related to shifting placement arrangements. In the fourth quarter of 2001, 19% of instrument placements were placed under third party leasing arrangements. Whereas in the first quarter of 2001, 64% were placed under third party leasing arrangements. Sales related to SurePath™ and

PrepStain™ systems accounted for 68% of total sales by the 4th quarter of 2001 as compared to 31% of total sales in 2000.

FDA approval to screen SurePath™ thin-layer slides using the FocalPoint™ Slide Profiler was a very significant event. FocalPoint™ related revenues declined in 2001 in large part because until approved for the screening of thin-layer slides it effectively competed against the ongoing U.S. market shift toward liquid-based testing. The decline in the number of tests performed on the FocalPoint™ corresponded with the general decline in conventional Pap smear testing in the U.S. in 2001. Subsequent to receiving FDA approval in October of 2001, we have leveraged the combined product to drive the sales of reagents and disposables. The FocalPoint™ now offers laboratories an effective platform to transition to thin-layer testing while realizing the clinical and economic benefits of computerized screening of both SurePath™ slides and conventional Pap smears. Within 120 days of receiving FDA approval, we secured integrated system agreements with 10 domestic customers. Multi-year agreements with DynaCare and U.S. Labs signed in the fourth quarter also include the complete i<sup>3</sup> Series™ product line.

We expect that along with the Canadian approval for SurePath™ and PrepStain™ (which has already led directly to multi-year agreements with the major commercial laboratories in Canada, including MDS and DynaCare) FDA approval for screening of SurePath™ thin-layer slides using the FocalPoint™ will provide a unique selling proposition and will help us to drive our reagent and disposable product sales in 2002 and beyond.

#### **THE i<sup>3</sup> SERIES™: What's Next**

An obvious advantage of a liquid based cell collection, preservation and transport system is the opportunity it may provide to perform testing that is adjunctive to cervical cytology screening. We were very pleased to report that Digene Corporation recently announced that it had filed a Pre-Market Approval Supplement application with the FDA for approval to use our SurePath™ Test Pack as a specimen collection medium for its "Hybrid Capture" 2 (hc2) HPV DNA Test for Human Papilloma Virus (HPV). Clinically, testing for HPV may be a valuable adjunctive test as follow-up to borderline cervical cytology test results. We also remain actively engaged in discussions with several companies regarding other adjunctive tests.

The FocalPoint™ GS further improves the screening process by automating the microscopic analysis of SurePath™ thin-layer slides or conventional Pap smears designated for further review by the FocalPoint™ Slide Profiler. The FocalPoint™ GS integrates our SlideWizard® technology into the FocalPoint™ screening process. We believe that the FocalPoint™ GS is a unique screening system that allows a laboratory to improve quality and to increase its testing capacity by up to 200%. All of our FocalPoint™ placements outside the U.S. now incorporate the FocalPoint™ GS feature. We anticipate completing clinical trials to obtain data to support an application for FDA approval of the FocalPoint™ GS in 2002.

#### **BD AND MILLENNIUM SELECT TRIPATH IMAGING**

In July of 2001, TriPath Imaging was selected by Becton, Dickinson and Company (BD) and Millennium Pharmaceuticals to develop and commercialize molecular diagnostics and pharmacogenomic tests for cancer as part of BD and Millennium's ongoing research and development program. BD invested \$25 million in TriPath Imaging through the purchase of 2,500,000 shares of TriPath Imaging common stock. A subsidiary of Millennium simultaneously acquired 400,000 shares of TriPath Imaging common stock in consideration for entering into a research license with us. We assumed operations of BD Gene, BD's research and development endeavor in the molecular diagnostics arena, and transferred its operations to North Carolina. We created TriPath Oncology, a wholly-owned subsidiary of TriPath Imaging, whose financial results are consolidated into TriPath Imaging to develop and commercialize molecular diagnostic and pharmacogenomic tests for malignant melanoma and cancer of the cervix, breast, ovary, colon, and prostate.



TriPath Imaging was selected by Becton, Dickinson and Company and Millennium Pharmaceuticals to develop and commercialize molecular diagnostics and pharmacogenomic tests for cancer

The core products and services we are developing through our collaboration with BD will be based upon genomic and proteomic markers identified primarily through research, conducted at Millennium, under its existing research and development agreement with BD. TriPath Oncology will clinically validate and develop these proprietary cancer markers into commercial diagnostic and pharmacogenomic oncology products and services. BD and TriPath Imaging share co-exclusive commercial rights for resulting products. BD will continue to fund additional discovery research activities at Millennium.

## TRIPATH ONCOLOGY

TriPath Oncology was created to translate discoveries from genomics and proteomics research into *molecular diagnostic and pharmacogenomic products designed to improve the clinical management of cancer. We now have active research and product development programs underway that will identify individuals with cancer at the earliest possible stage of disease, provide individualized predictive and prognostic information about disease state and outcome, guide treatment selection, and predict disease recurrence. We are developing a new family of molecular tests that have been developed on, or for, our proprietary imaging technologies.*



We believe that there are three key elements required to successfully develop and commercialize genomics based on oncology products: 1) identification and validation of novel molecular markers; 2) expertise in assay formatting and development; and 3) development of clinical instrumentation that will permit multiple and quantitative gene and protein expression analysis within cells. We believe that our proprietary assets and technologies in image analysis, together with the broad access to novel molecular markers offered through our relationship with BD and Millennium, will provide us with the necessary technology to successfully

develop improved diagnostic oncology products. We also believe that the establishment of TriPath Oncology as a separate business unit will provide the flexibility necessary to create an organization and dedicated management team with world-class skills and expertise in assay formatting and development, thereby fulfilling our vision for success in the molecular oncology diagnostics market.

In collaboration with BD and Millennium, we are mapping the key molecular changes that are associated with cancer presence, progression, stage and outcome. Through our joint efforts with our discovery partners, we will be able to better understand the role of genetic events and disease processes. Through the creation of TriPath Oncology, we now have a dedicated management team and organization with extensive oncology based experience and expertise in research, product development, and commercialization.

In our programs targeted at early cancer detection, we are identifying genes that are transcribed and expressed, which permit cancer specific detection early in the disease process, well before overt clinical symptoms appear. We will further leverage our knowledge in proteomics and genomics to develop tissue-based assays to create a molecular profile that is prognostic of disease stage and predictive of outcome and therapeutic response.

We have recently taken steps to initiate the commercial introduction of the first product developed by TriPath Oncology. We executed a letter of intent to collaborate with AmeriPath, Inc., a leading national provider of cancer diagnostics, genomic, and related information, on the validation and clinical use of a novel gene expression assay for malignant melanoma. As a leading provider of dermatopathology services in the U.S., AmeriPath was an obvious choice. AmeriPath has committed to leverage their unparalleled access to tissue and the collective knowledge base of their Dermatopathology Resource Committee to this collaboration. The test fits perfectly with their repertoire of technologies.

According to the terms of the letter of intent, AmeriPath will validate reagents and procedures to incorporate a novel gene target for malignant melanoma. The assay results will be analyzed using our SlideWizard® imaging and telepathology platform. We expect to finalize this arrangement in May of 2002, subject to obtaining various authorizations and approvals, as well as the negotiation and execution of a definitive agreement.

The American Cancer Society estimates that in 2001 approximately 51,400 new cases of malignant melanoma were diagnosed in the U.S. Although, melanoma accounts for only 5% of all skin cancers, it is responsible for more than 75% of deaths from skin cancer. The American Cancer Society estimates that approximately 7,800 persons will have died from melanoma in 2001. Our collaboration with AmeriPath represents a significant step toward providing broad market accessibility to novel markers for malignant melanoma.

We expect to begin commercial introduction of TriPath Oncology products and services for the staging and prognosis of cervical, breast and prostate cancer in 2004. Assays for early detection and monitoring of breast, ovarian, prostate, and colon cancer should follow in 2005. In the interim, we are actively investigating a number of potential strategic alliances to complement, accelerate, and augment the activities arising from our collaboration with BD.

## **NEXT STEPS**

We believe that we have created a very compelling business model. TriPath Imaging is an exciting company whose potential for value creation has been greatly enhanced by the bold steps that we have taken over the past year. We have clearly transformed this company.

Our approach, which combines an expanding commercial operation, our historic excellence in image analysis, and our newly developed strength in molecular diagnostics, is unique. We have strong partners and, entering into 2002, a strong cash position.

We believe that the steps taken in 2001 have positioned us well for 2002 and beyond. In 2002, we look forward to driving our Commercial Operations to profitability and to the development of new products and strategic relationships through TriPath Oncology.

We wish to thank our stockholders, our customers, and our employees for their support and commitment. Together we accomplished a great deal in 2001. We have articulated an ambitious plan.

**We are energized, focused,  
and committed, and look  
forward to 2002 and beyond”**

# INTEGRATING cervical cytology

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TriPath Care Technologies has been adopted to describe our commercial product offering and to communicate the broad nature of our corporate vision, as well as the value created by our growing product portfolio.

*TRiPATH*  
*care technologies™*

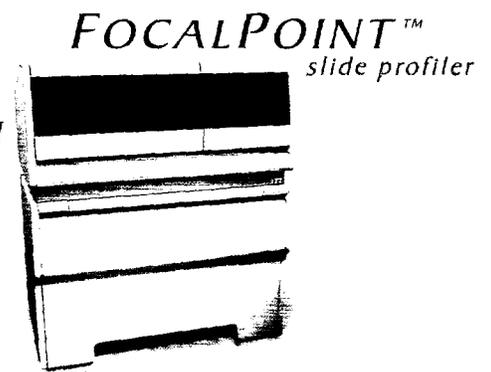
The products within our cervical cytology line were designed to be an integrated solution for the detection of cervical cancer and its precursor conditions; therefore the i<sup>3</sup> Series™ was created.

The silent exponent i<sup>3</sup> suggests the expertise contributed by each of our three predecessor companies, AutoCyte, NeoPath and NSI, as well as the value of these component products in providing intelligent identification through innovation. Within the i<sup>3</sup> Series™ line, individual products have been renamed to better communicate the value they provide to the physician, patients and laboratory professionals.

The i<sup>3</sup> Series™ line of cervical cytology products – "intelligent identification through innovation".

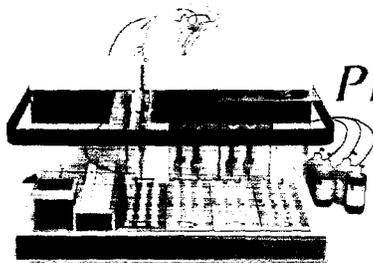


**SUREPATH™**  
test pack



**FOCALPOINT™**  
slide profiler

# **i<sup>3</sup> SERIES™**



**PREPSTAIN™**  
slide processor

## **SUREPATH™**

Formerly called CytoRich®. A proprietary, liquid-based cytology sample collection, cell preservation and transport system.

## **PREPSTAIN™**

Formerly know as the AutoCyte® Prep. An automated slide preparation system that produces slides with a standardized, thin layer of stained cervical cells.

>>PrepMate™, a PrepStain™ accessory, reduces the number of manual preparation steps required, to prepare samples for processing on the PrepStain™ instrument.

## **FOCALPOINT™**

Previously known as AutoPap® Primary Screener. Utilizes proprietary technology to distinguish between either normal thin-layer or normal conventional Pap smears and those that have the highest likelihood of abnormality.

We are committed to providing you with a comprehensive selection of cervical cytology solutions and are quickly emerging as the standard of excellence and efficiency in laboratory automation for anatomic pathology.

The first and only FDA  
Approved Integrated  
Cervical Cytology Solution

# TECHNOLOGY that lets you see more

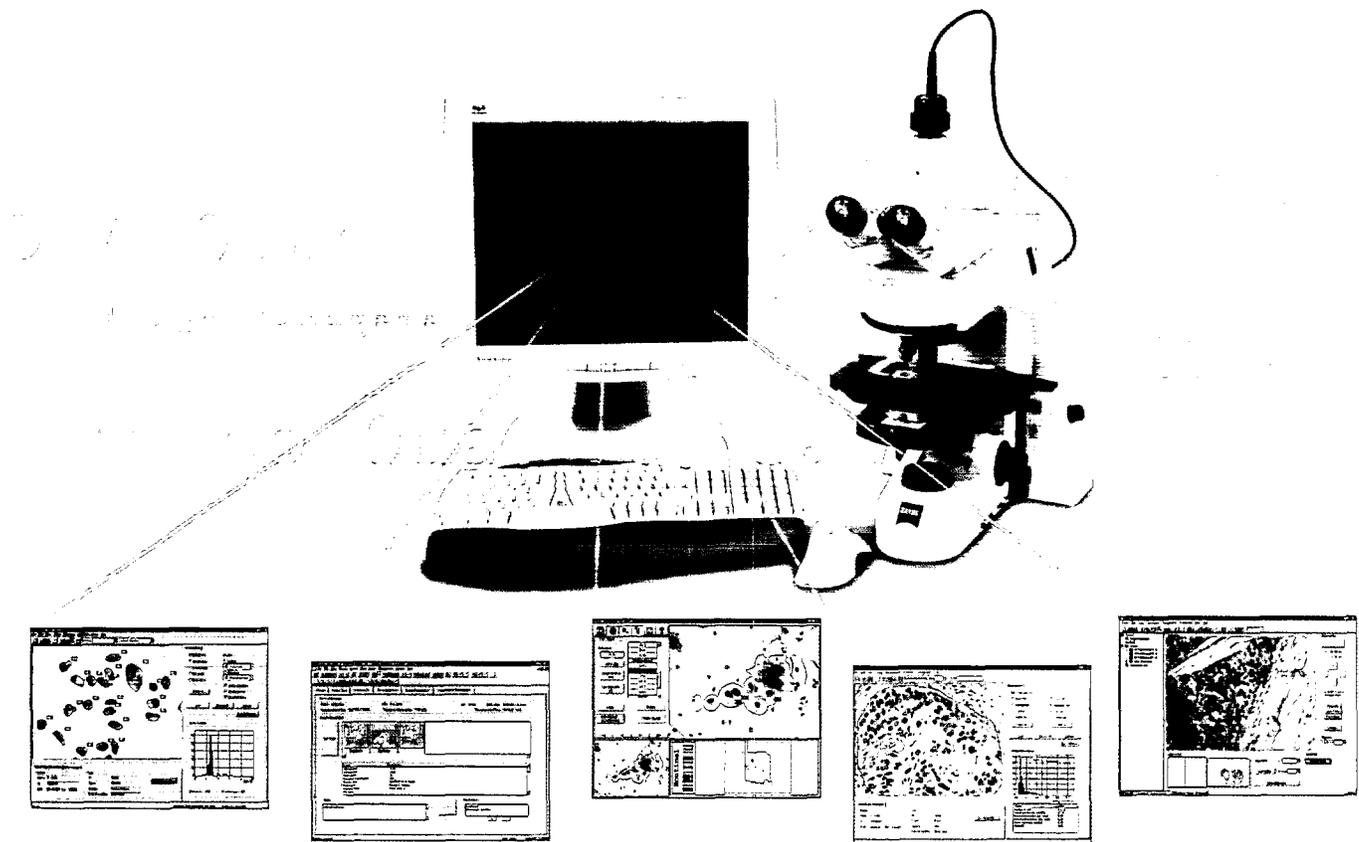
## *SLIDEWIZARD®* *Pathology Workstation*

TriPath Imaging's SlideWizard® pathology combines intellectual property with several individualized components, to create a flexible platform for existing and future applications.

SlideWizard® Applications: The standardized SlideWizard® platform allows you to choose applications that will meet your individual needs. The platform's ability to accept future TriPath Imaging applications, potentially reduces future capital equipment costs.

### **FOCALPOINT™ GS**

The FocalPoint™ GS integrates our SlideWizard® technology into the FocalPoint™ screening process. The FocalPoint™ instrument is interfaced to our SlideWizard® platform and networked to one or more commercially available microscopes that have been equipped with computer-controlled automated stages for fast relocation of "fields of interest" on microscopic slides. As with the FocalPoint™ Slide Profiler screening process, the FocalPoint™ GS identifies up to 25% of slides as "within normal limits" for which no further review is required. For each of the remaining slides, the FocalPoint™ communicates the location coordinates of the "fields of interest" to the computer controlled microscope stage via the SlideWizard® platform. The "fields of interest" are electronically highlighted for easy identification. This facilitates an abbreviated microscopic review and allows the cytotechnologist to quickly analyze the slide for the presence of cellular abnormality. Abnormal findings can be confirmed by full microscopic review. If no abnormality is identified during this rapid cytologic assessment, no further review is required.



### **DNA QUANTIFICATION**

Designed to support the user in the selection of cell targets and the quantitative assessment of a multitude of nuclear features including ploidy analysis.

### **IMMUNO QUANTIFICATION**

Designed to support the user in the selection of cell targets, and the quantitative assessment of immunologically marked cells. (Receptors/Proliferation).

### **IMAGE MANAGEMENT SYSTEM**

Combines easy to use image acquisition and archiving capabilities with sophisticated information management features.

### **TELEPATHOLOGY**

Provides a versatile system for microscopic image acquisition and telecommunication.

### **REVIEW ASSISTANT**

Interactive visual dotting method allows user to electronically "dot" the slide by storing x, y coordinates and annotate areas of interest. Subsequent review of slides allows user to automatically locate areas of interest utilizing a motorized stage.

# FOCUSING on the individual

TriPath Oncology was created on July 31, 2001, to research and translate discoveries in genomics and proteomics to develop products that improve the clinical management of cancer.

*TRiPATH*  
*ONCOLOGY*

With a specific goal of targeting early cancer detection, we are identifying genes that are transcribed and expressed which permit cancer specific detection early in the disease process, well before overt clinical symptoms appear. Our research team is currently focusing specifically in the areas of malignant melanoma, cervix, breast, ovarian, colorectal and prostate cancers.

In addition to our capabilities in biological research and product development, we also have significant internal expertise in image analysis as evidenced by our broad intellectual property estate, comprised of more than 100 issued US patents.

Treatments for cancer are expensive and oftentimes ineffective. Current treatments for cancer include surgery, radiation, and chemotherapy. Surgery is limited in its effectiveness, because it treats the tumor at a specific site and may not remove all the cancer cells at multiple sites. Surgery can also cause serious adverse side effects, because it may destroy healthy cells and tissues, as well as cancer cells. The American Cancer Society (ACS) projected that in 2001, approximately one half million Americans died of cancer-related illness, and that the five year relative survival rate for individuals diagnosed with cancer is about 60%. The National Institute of Health estimates that the overall costs of cancer-related illness in the US exceeded \$180 billion in 2000.

cervical  
breast  
colorectal

ovarian  
prostate  
melanoma

## STATISTICALLY SPEAKING

Through the establishment of TriPath Oncology, we have created a dedicated management team and world-class organization with extensive oncology based experience and expertise in research, product development and commercialization.

>>According to the World Health Organization (WHO), the worldwide incidence of cancer in the year 2000 exceeded 10 million cases, excluding basal and squamous cell cancers of the skin.

>>The WHO estimates approximately 6.2 million deaths worldwide in 2000 were attributable to cancer.

>>The American Cancer Society estimates that 1.3 million cases of non-skin cases were diagnosed in 2001.

>>In the United States, men have a 1 in 2 lifetime risk of developing cancer and women have a 1 in 3 risk.

>>The most frequently diagnosed cancers include cancer of the prostate, breast, lung and colon, which combined accounts for just over one half of all non-skin cancers diagnosed in the United States.

Worldwide incidence of cancer in the year 2000 exceeded 10 million cases

# FINANCIAL highlights

The selected consolidated financial data presented below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes thereto included in our Annual Report on Form 10-K.

## STATEMENT OF OPERATIONS DATA<sup>3</sup>

	Year ended December 31,				
	1997	1998	1999	2000	2001
Net sales	\$13,492	\$16,849	\$18,466	\$32,652	<b>\$27,017</b>
Gross profit	6,765	7,155	8,098	16,646	<b>14,070</b>
Research and development <sup>1</sup>	18,711	15,969	12,258	9,351	<b>8,534</b>
Selling, general and administrative	24,278	25,408	17,724	24,263	<b>28,220</b>
Operating loss	(36,224)	(37,307)	(33,251)	(16,968)	<b>(22,684)</b>
Net loss	\$(34,582)	\$(35,271)	\$(32,557)	\$(17,369)	<b>\$(21,680)</b>
Net loss per Share (basic and diluted) <sup>2</sup>	\$(1.91)	\$(1.46)	\$(1.17)	\$(0.60)	<b>\$(0.61)</b>
Weighted-average shares outstanding <sup>3</sup>	18,123	24,098	27,819	29,137	<b>35,467</b>

## BALANCE SHEET DATA<sup>3</sup>

Cash, cash equivalents and short-term investments	\$57,374	\$28,941	\$13,962	\$54,340	<b>\$55,976</b>
Working capital	64,881	32,553	17,338	62,316	<b>62,898</b>
Total assets	95,962	68,176	58,874	97,471	<b>96,748</b>
Long term obligations	151	2,051	1,117	3,760	<b>5,001</b>
Total stockholders' equity	\$88,255	\$55,075	\$47,025	\$80,774	<b>\$77,292</b>

\$ in thousands, except per share data

(1) Includes regulatory expenses.

(2) See Note 2 of Notes to our financial statements for information concerning the computation of net loss per share and shares used in computing net loss per share.

(3) The selected consolidated financial data has been restated to reflect the pooling transaction that occurred on September 30, 1999.

This annual report contains forward-looking statements, including our expectations regarding future revenues, earnings, projected plans, performance, the success of our management team, product development, commercialization and regulatory approval as well as other estimates related to future operations. The words or phrases "will likely result," "are expected to," "will continue," "is anticipated," "estimate," "project" or similar expressions are intended to identify "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934 and Section 27A of the Securities Act of 1933, as enacted by the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties that could cause our actual results for future periods to differ materially from any opinions or statements expressed with respect to future periods or events in any forward-looking statement. See "Important Factors Affecting Future Operating Results" attached as Exhibit 99.1 to our Annual Report on Form 10-K, which forms a part of this report.

1. 2019年12月31日  
2. 2020年1月1日  
3. 2020年1月1日  
4. 2020年1月1日  
5. 2020年1月1日